We Can Do This: An Assessment of the Department of Health and Human Services' COVID-19 Public Health Campaign

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I. Introduction

The House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations has conducted an investigation into the effectiveness and scientific accuracy of the "We Can Do This" COVID-19 vaccine promotional campaign ("Campaign") launched by the Department of Health and Human Services (HHS), in partnership with the Fors Marsh Group (FMG), which describes itself as a full-service behavior change research and strategy firm. This nationwide multimedia advertising campaign ran from August 2020 through June 2023 and cost over $900 million in taxpayer funds.[1]

Past public relations and media services contracts with HHS agencies have been the subject of Congressional and Inspector General scrutiny. In 2020, the HHS's Office of Inspector General (OIG) found that senior leaders at the Centers for Medicare and Medicaid Services (CMS) did not comply with federal acquisition requirements and did not properly manage personal services contracts related to media consulting for the CMS Administrator.[2] Although the Government Accountability Office (GAO) cleared CMS of statutory violations, the OIG's analysis highlighted wider concerns of fiscal mismanagement.[3] In 2013, this Committee investigated the National Institutes of Health (NIH) communications and public relations funding after an article by *The Cancer Letter* reported that, in 2012, the NIH's National Cancer Institute (NCI) spent over $45 million on communications, which was almost double the amount the entire U.S. Food and Drug Administration (FDA) spent during the same period.[4] The historic overspending and mismanagement of taxpayer funds by HHS and its agencies on past public relations and media services contracts, as well as the substantial funds involved in the "We Can Do This" Campaign, prompted the Committee to once again scrutinize HHS's contracting activities.

In August 2020, as Operation Warp Speed (OWS) was in the final stages of vaccine trials, the HHS's Office of the Assistant Secretary for Public Affairs (ASPA) initiated a COVID-19 public education campaign called the "We Can Do This" Campaign to shape the public's response to the COVID-19 pandemic, including vaccine uptake, masking, social distancing and booster vaccine uptake.[5] To execute this Campaign, ASPA awarded three task orders to FMG through the

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[1] Fors Marsh Group, FMG000001 (on file with Committee).
[2] Dep't of Health & Hum. Servs. Off. of the Inspector Gen'l, *CMS Did Not Administer and Manage Strategic Communications Services Contracts in Accordance with Federal Requirement*, A-12-19-20003 (July 2020). https://oig hhs.gov/oas/reports/region12/121920003.pdf.
[3] U.S. Gov't Accountability Office, B-332531, U.S. Department of Health and Human Services—Obligations for Communication Services 1, 9 (2023), https://www.gao.gov/products/b-332531.
[4] Kaiser, Jocelyn, *House Committees Probe NIH Spending on Public Relations,* Science (Apr. 15, 2013), https://www.science.org/content/article/house-committees-probe-nih-spending-public-relations.
[5] U.S. Gov't Accountability Off., GAO-22-104724, COVID-19: Information on HHS Public Education Campaign 1, 7 (2022), https://www.gao.gov/products/gao-22-104724.

"Public Information and Communication Services II" (PICS II) contract vehicle.[6] While ASPA initiated the Campaign, FMG adhered to COVID-19-related guidance and recommendations made by the Centers for Disease Control and Prevention (CDC) when developing content for the Campaign. An in-depth discussion of the Campaign's launch, as well as its outreach and engagement strategies can be found in the Appendix.

The "We Can Do This" Campaign's primary goal was to increase public confidence in, and uptake of, the COVID-19 vaccine, including booster shots, among the American people. The Campaign also sought to "bolster optimism, counter despair, and bring people together" utilizing "[f]inely honed, timely messages [to] inspire confidence and mobilize a nation eager for normalcy to adopt behaviors that stem the spread of the virus and speed economic recovery."[7] To this end, the Campaign sought to address the "explosion of misinformation that feeds mistrust of scientific and public health communities, and of public servants throughout the ranks of government" by "influenc[ing] behaviors around COVID-19 and the seasonal flu and prepar[ing] for a safe and prosperous reopening."[8]

Based on reports shared with the Committee, FMG spent on average over $20 million per month for the design and execution of the Campaign.[9] In its proposal for the task order, the company asserted that it could benefit ASPA by using a strategic mix of paid and earned media with exclusive radio partnerships, research-based messaging, and reinforced messaging from trusted influencers, celebrities, and sports figures.[10] FMG's Campaign strategies were grounded in several theories of behavior change and communication, "with the expectation that exposure to Campaign messages prompts change in cognitions antecedent to Campaign-targeted behavior."[11] The health belief model, used by the Campaign, posits that "a person's belief in a personal threat of an illness or disease together with a person's belief in the effectiveness of the recommended health behavior or action will predict the likelihood the person will adopt the behavior."[12]

Utilizing protocols and practices from prior FDA and CDC-led public health campaigns for tobacco prevention and control, FMG and its partners created ads and designed outreach

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[6] The PICS II contract is awarded as an Indefinite Delivery, Indefinite Quantity contract. In 2018, ten vendors were selected to participate in the PICS II contract. Once selected, the vendors could then submit proposals for individual task orders from NIH and other HHS components for specific communications services such as assistance with graphic design, web development, materials distribution, conference support, and media relations.
[7] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000498 (Aug. 14, 2020) (on file with Committee).
[8] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000499 (Aug. 14, 2020) (on file with Committee).
[9] Fors Marsh Group, VacciNation Forward, FMG000528 (July 16, 2021) (on file with Committee).
[10] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000498 (Aug. 14, 2020) (on file with Committee).
[11] Elissa C. Kranzler et al., *Recalled Exposure to COVID-19 Public Education Campaign Advertisements Predicts COVID-19 Vaccine Confidence*, 28 J. of Health Commc'n. 144, 145 (2023), https://www.tandfonline.com/doi/full/10.1080/10810730.2023.2181891.
[12] *The Health Belief Model*, Boston University School of Public Health (Nov. 3, 2022), https://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories2 html.

strategies that specifically targeted different demographic groups and population segments.[13] In short, FMG planned to use CDC guidance, recommendations, and internal scientific research to create advertising material to convince the American people that COVID-19 posed a sufficient threat to them or their loved ones and that they should follow the government's recommendations and mandates. To be credible, the underlying HHS and CDC scientific recommendations and guidance needed to be effective at reducing the risk of COVID-19. Moreover, HHS and CDC needed to themselves remain credible communicators to the public.

Over the course of its existence, the Campaign came to serve as a critical vehicle for disseminating the Biden-Harris administration's messaging on mask usage, social distancing, vaccine effectiveness, the risks COVID-19 posed to children, and how to reopen schools, businesses, and civil society. As the Committee of jurisdiction over public health, it is important for the Committee—and federal public health entities—to understand why the Campaign led to a loss of public trust in HHS and its agencies, as well as consider reforms that will prevent a repeat of the same failure during potential future public health emergencies. This report is a chronological examination of ads, blog posts, and other public relations material produced for the "We Can Do This" Campaign and overlays Campaign activity with critical events during the Biden-Harris administration's response to the pandemic.

A. Objectives of the Report and Summary of Findings

The overall goal of this report is to understand why, with the extent of these resources, the Campaign and the Biden-Harris administration's response to the pandemic resulted in a collapse of the public's trust in public health messaging.

Much of the scientific content directly featured in or alluded to in Campaign ads and other promotional material was drawn from CDC recommendations, guidance, and research, critical parts of which proved to be deeply flawed. The CDC's errors and failures to update recommendations and guidance were reflected in the "We Can Do This" ads and promotional materials:

- CDC's guidance, which the Campaign relied on, went beyond the terms of FDA's Emergency Use Authorization (EUA) to state, without evidence, that COVID vaccines were highly effective against transmission. This ultimately had a negative impact on vaccine confidence and the CDC's credibility when proven untrue.[14]

[13] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000505 (Aug. 14, 2020) (on file with Committee).
[14] *See infra* December 2020: FDA Approval of First COVID-19 Shots, pgs. 8-9, CDC Overstates the Effectiveness of the Vaccine at Preventing Infection and Transmission, pgs. 20-21, CDC Director Walensky Doubles Down and then Walks Back, pgs. 24-27.

- The CDC had inconsistent and flawed messaging about the effectiveness of masks.[15]

- The CDC consistently overstated the risk of COVID-19 to children.[16]

- The CDC continues to recommend COVID-19 vaccines for all Americans ages six months and older, which has made the United States a global outlier in COVID-19 policy.[17]

B. Summary of Recommendations[18]

Americans cannot afford another botched government response to a future pandemic. In order to prevent a recurrence of HHS's failures in public relations management for the COVID-19 pandemic response and to strengthen the nation's public health preparedness system, the Committee makes the following recommendations:

- Congress should consider formally authorizing the CDC and clearly define the agency's core mission.

- HHS and its agencies should abide by the FDA's product labeling guidelines. HHS and its agencies should be barred from promoting information regarding an FDA-regulated product that does not reflect the FDA-approved label.

- Congress should consider clarifying responsibility for evaluating the safety of vaccines and streamline existing reporting systems for capturing vaccine injuries and adverse reactions.

- HHS and its agencies should embrace a culture of transparency and accountability.

- HHS and public health officials should not attempt to silence dissenting scientific opinions.

- HHS and its agencies should overhaul their website archival process to mimic that of prior White House administrations.

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[15] *See infra* In the First Six Months of 2020, CDC Flip-Flops on its Mask Wearing Guidance, pgs. 9-13, CDC Overstates the Effectiveness of the Vaccine at Preventing Infection and Transmission, pgs. 20-21, and CDC Admits Existence of Breakthrough Cases and Wants Masks Back On, pgs. 31-35.
[16] *See infra* Vaccines and Boosters Approved for Young Children (5-11 Years), pgs. 40-42, CDC Admits to Overcounting COVID-19 Deaths, pgs. 63-64, and The Biden Administration Aggressively Pushed Boosters for Children and Adolescents, pgs. 64-65.
[17] *See infra* CDC Goes it Alone, Recommends COVID-19 Shots for Children Six Months to Four Years, Followed by Universal Booster Campaign, pgs. 65-72.
[18] For a detailed discussion on Recommendations, *see* pgs. 72-75.

II. Winter 2020—2021: The Foundations of Failure

The COVID-19 Pandemic and Federal Response in the Months Leading Up to the Launch of the "We Can Do This" Campaign

A. December 2020: FDA Approval of First COVID-19 Shots

Both during his campaign for President and after assuming office, President Biden repeatedly promised to "follow the science," put public health officials in charge of the COVID-19 response, and to "shut down the virus, not the country."[19] President Biden had at his disposal trillions of dollars in federal emergency funding.[20] Given all the resources and scientific expertise available, it is not surprising that President Biden and his advisors anticipated the pandemic would be over by Independence Day 2021.[21]

On December 11, 2020, the FDA issued an emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine.[22] The FDA followed this authorization with an EUA for the Moderna COVID-19 Vaccine on December 18, 2020.[23] Both shots were authorized for individuals 16 years and older.

In issuing the EUA for the Pfizer-BioNTech vaccine, the FDA summarized the available clinical data supporting the EUA:

> The effectiveness data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial

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[19] ABC News, *Joe Biden: "Let's End the Politics and Follow the Science"*, Facebook (Oct. 6, 2020) https://www facebook.com/ABCNews/videos/joe-biden-lets-end-the-politics-and-follow-the-science/375786760107301/; Joe Biden (@JoeBiden), X (formerly Twitter) (Oct. 22, 2020, 9:22 PM), https://twitter.com/JoeBiden/status/1319448963443982337?lang=en.

[20] Grace Segers, *Biden Signs $1.9 Trillion American Rescue Plan into Law*, CBS News (Mar. 12, 2021), https://www.cbsnews.com/news/biden-signs-covid-relief-bill-american-rescue-plan-into-law/.

[21] Domenico Montanaro & Chloee Weiner, *Biden Sets Goal of July 4th To 'Mark Independence' from Coronavirus,* NPR News (Mar. 11, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/03/11/975420676/biden-to-address-the-nation-marking-1-year-of-coronavirus-pandemic.

[22] Press Release, U.S. Food & Drug Admin. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[23] Press Release*,* U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020)*,* https://www fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

> participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. Of these 170 COVID-19 cases, one in the vaccine group and three in the placebo group were classified as severe. **At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person** (emphasis added).[24]

With respect to the Moderna vaccine, the FDA reported a similar level of protection at 94.1 percent.[25] Like the EUA for the Pfizer BioNTech vaccine, the Moderna EUA noted, "**At this time, data are not available to determine how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person** (emphasis added)."[26]

On February 27, 2021, the FDA issued an EUA for Janssen's COVID-19 Vaccine.[27] Like the previous two EUAs, the authorization for Janssen's COVID-19 Vaccine stated that there was **no available evidence "that the vaccine prevents transmission of SARS-CoV-2 from person to person** (emphasis added)."[28] In short, the clinical trials supporting all three EUAs showed that the vaccines provided statistically significant levels of protection from COVID-19 infection for a period of three months. But there was no evidence that the vaccines prevented infection after this time or that the vaccines prevented COVID transmission from person to person.

i. In the First Six Months of 2020, CDC Flip-Flops on its Mask Wearing Guidance

Between January and March of 2020, federal public health officials, including some at the CDC, strongly opposed the widespread use of masks for the general public because they were ineffective in preventing transmission of SARS-CoV-2. On January 21, 2020, one day after the first instance of human-to-human COVID-19 transmission in the United States was confirmed, Dr.

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[24] *Id.*
[25] Colin Pawlowski et al., *FDA-Authorized mRNA COVID-19 Vaccines Are Effective Per Real-World Evidence Synthesized Across a Multi-State Health System,* Nat'l Libr. of Med. (Jun. 29, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8238652/.
[26] Press Release, U.S. Food & Drug Admin. FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid#:~:text=At%20this%20time%2C%20data%20are,2%20from%20person%20to%20person.
[27] Press Release, U.S. Food & Drug Admin. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.
[28] *Id.*

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Disease, said, "We do not currently recommend the use of face masks for the general American public. This virus is not spreading in your communities."[29] In February 2020, former U.S. Surgeon General Jerome Adams tweeted, in a post that has since been deleted, "Seriously people- STOP BUYING MASKS! They are NOT effective in preventing general public from catching #Coronavirus, but if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk!"[30]

Dr. Anthony Fauci, former head of the National Institute of Allergies and Infectious Diseases (NIAID), advocated against mask wearing on February 5, 2020, stating "Masks are really for infected people to prevent them from spreading infection to people who are not infected rather than protecting uninfected people from acquiring infection."[31]

Similarly, in March 2020, the World Health Organization (WHO) discouraged people from buying or using face masks unless they were sick with COVID-19 or were caring for someone who was sick. At a media briefing, Dr. Mike Ryan, executive director of the WHO health emergencies program said, "There is no specific evidence to suggest that the wearing of masks by the mass population has any potential benefit. In fact, there's some evidence to suggest the opposite in the misuse of wearing a mask properly or fitting it properly."[32] He and other WHO officials also expressed concern at the "massive global shortage" of masks available for frontline health workers due to mask hoarding by the public.[33]

The CDC website stated that "only people who need to wear a face mask are those who are sick or are caring for someone who is sick and unable to wear a mask."[34] Moreover, infectious disease specialists warned face coverings and masks would create a false sense of security by making the public believe they were "invulnerable to their environment."[35] As early as July 2020,

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[29] Dr. Rob Davidson, *COVID-19 Mask Guidance in America Has Evolved- But Rejecting Science isn't the Answer*, NBC News (Aug. 8, 2020), https://www nbcnews.com/think/opinion/covid-19-mask-guidance-america-has-evolved-rejecting-science-isn-ncna1235472.

[30] Leah Asmelash, *The Surgeon General Wants Americans to Stop Buying Face Masks*, CNN (Mar. 2, 2020), https://www.cnn.com/2020/02/29/health/face-masks-coronavirus-surgeon-general-trnd/index.html.

[31] Samuel Chamberlain, *Fauci Emails Show His Flip-Flopping on Wearing Masks to Fight COVID*, N.Y. Post (June 3, 2020), https://nypost.com/2021/06/03/fauci-emails-show-his-flip-flopping-on-wearing-masks-to-fight-covid/.

[32] Jacqueline Howard, *WHO Stands by Recommendation to not Wear Masks if You are not Sick or not Caring for Someone Who is Sick*, CNN (Mar. 31, 2020), https://www.cnn.com/2020/03/30/world/coronavirus-who-masks-recommendation-trnd/index html.

[33] *Id.*

[34] Huo Jingnan et al., *Should We All Be Wearing Masks in Public? Health Experts Revisit the Question*, NPR News (Mar. 31, 2020), https://www npr.org/sections/health-shots/2020/03/31/824560471/should-we-all-be-wearing-masks-in-public-health-experts-revisit-the-question.

[35] KCAL News, *Experts Warn Masks Can Give Some False Sense of Security, Encourages People to Socially Distance*, CBS News (July 7, 2020), https://www.cbsnews.com/losangeles/news/masks-scientists-covid-19-airborne/.

a California assemblymember expressed her shock and disappointment that she had been infected with COVID-19 while indoors, despite masking.[36]

By April 3, 2020, the CDC completely reversed course and announced new mask wearing guidelines, recommending that all people wear a mask outside of the home.[37] On July 14, 2020, the CDC again called on the public to wear cloth face masks outdoors, calling masks "a critical tool in the fight against COVID-19."[38] This initial reversal was a precursor to future reversals and inconsistencies in the CDC's messaging on COVID-19 related issues, that would eventually cause much of the public to lose trust in the CDC.

After the CDC endorsed widespread masking for the general public in April 2020, Dr. Fauci publicly approved the agency's new stance. On July 17, 2020, on a live-streamed event hosted by the U.S. Chamber of Commerce, Dr. Fauci, in a clear reversal of his earlier statement that masks did not protect "uninfected people from acquiring infection" said, "I would urge the leaders—the local political and other leaders—in states and cities and towns to be as **forceful as possible** in getting your citizenry to wear masks" (emphasis added).[39] Three months later, Dr. Fauci voiced support for a national mask mandate, calling on governors and mayors to "do it locally if it's not done nationally."[40] When a federal judge struck down the CDC's mask mandate on public transportation systems, Dr. Fauci called the ruling "disturbing," and stated the mask mandate was "not a judicial matter" and was setting a "dangerous precedent."[41]

Only in January 2022 did the CDC update its masking guidelines, finally acknowledging for the **first time in two years,** that cloth masks and face coverings "do not offer as much protection as surgical masks or respirators."[42] At that time, around half of the country's 53 million children remained compulsorily masked.[43] Many states closely followed CDC guidance and required masks for students of all ages, regardless of vaccination status. Some localities went

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[36] *Id*.
[37] *CDC Museum COVID-19 Timeline*, CDC: David J. Spencer CDC Museum: In Association with the Smithsonian Institution, https://www.cdc.gov/museum/timeline/covid19 html (last visited Oct. 18, 2024).
[38] *Id.*
[39] Jessie Hellmann, *Fauci Urges State, Local Leaders to 'Be as Forceful as Possible' on Masks*, The Hill (July 17, 2020), https://thehill.com/policy/healthcare/507838-fauci-urges-state-local-leaders-to-be-as-forceful-as-possible-on-masks/.
[40] Caitlin O'Kane, *Fauci Voices Support for National Mask Mandate*, CBS News (Oct. 29, 2020), https://www.cbsnews.com/news/fauci-mask-mandate/.
[41] Shawna Chen, *Fauci: Travel Mask Mandate Ruling Could Set "Dangerous Precedent"*, Axios (Apr. 21, 2022), https://www.axios.com/2022/04/22/fauci-travel-mask-mandate-ruling; Brad Dress, *Fauci: Judge's Decision to Strike Down Travel Mask Mandate Could Set 'Disturbing' Precedent*, The Hill (Apr. 21, 2022), https://thehill.com/opinion/congress-blog/healthcare/3459265-fauci-judges-decision-to-strike-down-travel-mask-mandate-could-set-disturbing-precedent/.
[42] Apoorva Mandavilli, *The C.D.C. Concedes That Cloth Masks do not Protect Against the Virus as Effectively as Other Masks.*, N.Y. Times (Jan. 15, 2022), https://www.nytimes.com/2022/01/14/health/cloth-masks-covid-cdc html.
[43] Margery Smelkinson et al.,*The Case Against Masks at School*, The Atlantic (Jan. 26, 2022), https://www.theatlantic.com/ideas/archive/2022/01/kids-masks-schools-weak-science/621133/.

beyond CDC guidance, requiring masks for students outdoors at recess.[44] Most masks worn by children were cloth masks which, by the CDC's own admission, did not offer significant protection against viral spread.[45] In response to the January 2022 updated guidance from the CDC, some school districts updated their mask policy to exclude cloth masks, with states issuing child sized KN95 masks to schools.[46]

Parents who voiced concerns about the long-term implications of masking their young children and advocated for the CDC to ease masking guidelines for young children became social pariahs and were labeled "psychotic, anti-vax right-winger[s]."[47] Moreover, the CDC touted unreliable data in the press to justify its policy to mask millions of children.[48] Critics panned the CDC, stating the "agency's decision to trumpet [. . .] dubious findings, and subsequent lack of transparency, raise questions about its commitment to science-guided policy."[49] In other instances, when researchers tried to replicate the CDC's highly promoted studies in favor of masking school children, with a larger, more representative sample size and over a longer time period, they failed to find any significant correlation that school mask mandates lead to a reduction in pediatric COVID-19 cases.[50]

In March of 2022, a poll conducted by *Politico* and the Harvard T.H. Chan School of Public Health found that "a substantial proportion of parents" whose children's schools implemented a mask mandate at any time during the school year believed masks had negatively impacted their child's well-being.[51] Specifically, the poll found 46 percent of parents believed mask mandates hurt their children's social learning and interactions, 40 percent believed mask mandates hurt their children's general schooling experience, 39 percent believed mask mandates negatively affected their child's mental and emotional health, and 33 percent believed masks hurt their children's education.[52] A November 2021 commentary in the journal *Public Health in Practice* called the Biden-Harris administration's policy to mask preschool children "bad public health" and raised

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[44] *Id.*
[45] Apoorva Mandavilli, *The C.D.C. Concedes That Cloth Masks do not Protect Against the Virus as Effectively as Other Masks supra* note 42; NIOSH, Community Respirators and Masks, CDC, https://www.cdc.gov/niosh/topics/publicppe/community-ppe html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprevent-getting-sick%2Ftypes-of-masks.html#anchor_5146932324 (last accessed Oct. 18, 2024).
[46] Anya Kamenetz, *After 2 Years, Growing Calls to Take Masks Off Children in School*, NPR (Jan. 28, 2022), https://www npr.org/2022/01/28/1075842341/growing-calls-to-take-masks-off-children-in-school.
[47] *Id.*
[48] David Zweig, *The CDC's Flawed Case for Wearing Masks in School*, The Atlantic (Dec. 16, 2021), https://www.theatlantic.com/science/archive/2021/12/mask-guidelines-cdc-walensky/621035/.
[49] *Id.*
[50] Ambarish Chandra & Tracy Beth Høeg, *Lack of Correlation Between School Mask Mandates and Paediatric COVID-19 Cases in a Large Cohort*, 85 J. of Infection 671-675 (Sept. 29, 2022), https://www.journalofinfection.com/article/S0163-4453(22)00550-3/fulltext.
[51] Conflicting Views Among Parents About the Impact on Their Children of Continuing Mask Mandates in Schools, Politico-Harvard T.H.Chan Sch. of Pub. Health (March 2022), https://www.politico.com/f/?id=0000017f-bdbf-d17b-a1ff-bfff54ea0000.
[52] *Id.*

the alarm on the devastating impacts of these policies on early childhood development.[53] Overall, long term use of face masks by young children can affect speech development, brain development, and inhibit social interactions.[54] Studies have found mask wearing during the COVID-19 pandemic has led to "a profound deficit in face perception abilities,"[55] particularly in school-age children whose face perception abilities are not fully developed, as well as on children's emotion recognition accuracy.[56]

In December of 2022, after leaving the Biden White House, former COVID-19 coordinator, Ashish Jha, freely admitted what many had been saying all along—"[t]here is no study in the world that shows that masks work that well."[57]

B. January 2021: Biden Imposes Mask Mandate for Domestic and International Travel

On January 21, 2021, his first full day in office, President Biden signed Executive Order 13998, titled *Promoting COVID-19 Safety in Domestic and International Travel*, which imposed a mask mandate on most forms of domestic and international travel.[58] In implementing the mask mandate, the Department of Transportation ordered that everyone ages two and older be required to wear a mask while traveling.[59] The Executive Order also required U.S. citizens and lawful permanent residents to have a negative COVID-19 test prior to returning home from abroad.[60] The

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[53] Robert C. Hughes et al., *Making Pre-School Children Wear Masks is Bad Public Health*, 2 Pub. Health in Prac. 100197 (2021), https://www.sciencedirect.com/science/article/pii/S2666535221001221.

[54] Robert C. Hughes et al., *Making Pre-School Children Wear Masks is Bad Public Health*, 2 Pub. Health in Prac. 100197 (2021), https://www.sciencedirect.com/science/article/pii/S2666535221001221; Anya Kamenetz, *After 2 Years, Growing Calls to Take Masks Off Children in School*, NPR (Jan. 28, 2022), https://www npr.org/2022/01/28/1075842341/growing-calls-to-take-masks-off-children-in-school; Vinay Prasad, *The Downsides of Masking Young Students Are Real*, The Atlantic (Sept. 2, 2021), https://www.theatlantic.com/ideas/archive/2021/09/school-mask-mandates-downside/619952/.

[55] Andreja Stajduhar et al., Cognitive Res.: Principles and Implications, Face Masks Disrupt Holistic Processing and Face Perception in School-Age Children (Feb. 7, 2022), https://cognitiveresearchjournal.springeropen.com/articles/10.1186/s41235-022-00360-2.

[56] Lorna Bourke et al., *The Effect of Face Mask Wearing on Language Processing and Emotion Recognition in Young Children*, 226 J. of Experimental Child Psych 105580 (2023), https://www ncbi nlm nih.gov/pmc/articles/PMC9637007/.

[57] Zachary Stieber Epoch Health, *White House COVID Czar Admits Masks Don't Work*, Desert Review (Dec. 23, 2022), https://www.thedesertreview.com/white-house-covid-czar-admits-masks-dont-work/article_8ffc2d7e-82ec-11ed-b3fe-379aa32369df html.

[58] Press Release, President Biden, Executive Order on Promoting COVID-19 Safety in Domestic and International Travel (Jan. 21, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-promoting-covid-19-safety-in-domestic-and-international-travel/.

[59] Press Release, Dep't of Transp., TSA to Implement Executive Order Regarding Face Masks at Airport Security Checkpoints and Throughout the Transportation Network (Jan. 31, 2021), https://www.tsa.gov/news/press/releases/2021/01/31/tsa-implement-executive-order-regarding-face-masks-airport-security.

[60] Exec. Order No. 13998, Promoting COVID-19 Safety in Domestic and International Travel, 86 Fed. Reg. 7205 (Jan. 26, 2021), https://www federalregister.gov/documents/2021/01/26/2021-01859/promoting-covid-19-safety-in-domestic-and-international-travel; Ctr. for Disease Control & Prevention Dep't of Health & Hum. Servs.,

Biden-Harris administration also required foreign nationals entering the country legally to have a negative COVID-19 test prior to entry.[61] However, the Biden-Harris administration did not impose the same testing requirements on those entering the country illegally, which undermined the importance of then-existing COVID-19 protocols.[62] Although international COVID-19 testing requirements were dropped in June of 2022[63], President Biden's Executive Order remained in place until April 12, 2024.[64]

Executive Order 13998—the fulfillment of a campaign pledge by then-candidate Biden—would eventually be found unconstitutional by a federal court in April of 2022.[65]

C. February 2021: CDC Issues School Re-Opening Guidance Influenced by Teachers' Unions

On February 18, 2021, the CDC released school re-opening guidance that, if implemented, would have prevented "more than 90% of schools in the United States, including in almost all of the 50 largest counties in the country, from fully reopening."[66] Doctors who reviewed the guidance expressed dismay that the CDC's newly released guidance would continue to keep schools closed for months, even after they could realistically reopen safely.[67]

Freedom of Information Act (FOIA) requests and Congressional investigations later revealed CDC's school reopening guidance was influenced by the American Federation of Teachers' (AFT) President, Randi Weingarten. Weingarten received direct access to then-CDC

Requirement for Persons to Wear Masks While on Conveyances & at Transportation Hubs (Jan. 29, 2021), https://web.archive.org/web/20210130073435/https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf.

[61] Exec. Order No. 13998, Promoting COVID-19 Safety in Domestic and International Travel.

[62] Frances Robles & Miriam Jordan, *Covid on the Border: Migrants Aren't Tested on Arrival in U.S.*, N. Y. Times (Apr. 28, 2021), https://www.nytimes.com/2021/04/28/us/coronavirus-migrants-testing html; Callie Patteson, *WH Defends Not Requiring Negative COVID Test from Illegal Migrants*, N.Y. Post (Sept. 20, 2021), https://nypost.com/2021/09/20/wh-defends-not-requiring-neg-covid-test-from-illegal-migrants/.

[63] Zeke Miller & David Koenig, *US Lifts COVID-19 Test Requirement for International Travel*, AP News (June 10, 2022), https://apnews.com/article/covid-health-travel-government-and-politics-air-af509c58df1c931caac6ecf957ea1aed.

[64] Exec. Order No. 14122, Executive Order on COVID-19 and Public Health Preparedness and Response, 89 Fed. Reg. 27355 (Apr. 17, 2024), https://www federalregister.gov/documents/2024/04/17/2024-08332/covid-19-and-public-health-preparedness-and-response.

[65] *Health Freedom Def. Fund v. Biden*, 599 F. Supp. 3d 1144, 1173-73 (M.D. Fla. 2022) (holding the CDC failed to provide reasoned explanation for "rejecting alternatives and for its system of exceptions" and finding that the imposition of the mask mandate was "arbitrary and capricious").

[66] Will Feuer, *CDC's Classroom Guidance Would Keep 90% of Schools at Least Partially Closed*, CNBC News (Feb. 18, 2021), https://www.cnbc.com/2021/02/18/cdcs-classroom-guidance-would-keep-90percent-of-schools-at-least-partially-closed html.

[67] *Id.*

Director Rochelle Walensky. Through this quiet backchannel to the CDC, the AFT was directly able to edit guidance and push for prolonged school closures.[68]

A month prior to the CDC releasing its teachers'-union-influenced school reopening guidance, United Nations International Children's Emergency Fund (UNICEF) Executive Director Henrietta Fore issued a statement condemning school closures:

> As we enter the second year of the COVID-19 pandemic, and as cases continue to soar around the world, no effort should be spared to keep schools open or prioritize them in reopening plans . . . Despite overwhelming evidence of the impact of school closures on children, and despite increasing evidence that schools are not drivers of the pandemic, too many countries have opted to keep schools closed, some for nearly a year… That's why closing schools must be a measure of last resort, after all other options have been considered . . . In case of lockdowns, schools must be among the first to reopen once authorities start lifting restrictions.[69]

Because of the political power that teachers' unions exercised over the Biden-Harris administration, as well as over Democrat-led states and localities, the United States experienced some of the longest school closures in the world.[70] School closures throughout the country were not uniform. While some students, primarily in Republican-led states and in rural areas, returned to school by the fall of 2020, others, in Democrat-led states and big cities, would not set foot into

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[68] Victor Nava, *AFT Boss Randi Weingarten Questioned Language in School Reopening Plan in Chummy Exchange with CDC Chief, Texts Show,* N.Y. POST (June 2, 2023), https://nypost.com/2023/06/02/texts-reveal-exchange-between-cdc-director-teachers-union-boss-before-school-reopening-memo/; Joe Nocera, *CDC Still Getting Interference. This Time from Teachers.*, Bloomberg (May 4, 2021), https://www.bloomberg.com/opinion/articles/2021-05-04/cdc-emails-with-teachers-union-show-politics-still-trump-science.

[69] Georgina Diallo, *Children Cannot Afford Another Year of School Disruption*, UNICEF (Jan. 12, 2021), https://www.unicef.org/press-releases/children-cannot-afford-another-year-school-disruption.

[70] Meira Levinson & Daniel Markovits, *The Biggest Disruption in the History of American Education*, The Atlantic (June 23, 2022), https://www.theatlantic.com/ideas/archive/2022/06/covid-learning-loss-remote-school/661360/; Rebecca Jack & Emily Oster, *Covid-19 Hit Hardest at the Most Vulnerable. So did School Closures*, Education Next (Jan. 17, 2024), https://www.educationnext.org/covid-19-hit-hardest-at-the-most-vulnerable-so-did-school-closures/; Alasdair Munro et al., *In-person Schooling is Essential Even During Periods of High Transmission of COVID-19*, BMJ Evidence-Based Medicine 28, 175-79 (2023), https://ebm.bmj.com/content/28/3/175.

a school building until the fall of 2021, a full year after their peers.[71] The weight of the evidence now shows that "extended school closures did not significantly stop the spread of Covid, while the academic harms for children have been large and long-lasting."[72] By contrast, President Trump had emphasized the need for schools to be reopened in the fall of 2020, for the welfare of children and parents alike.[73]

> *Taking 50 million children out of classrooms at the beginning of the pandemic* ***"may prove to be the most damaging disruption in the history of American education."***
>
> **The New York Times**

The Biden-Harris administration's school closures were a failed policy with devastating consequences. Studies have since shown school closures and remote instruction contributed to widening achievement gaps, with the most disadvantaged students seeing the largest declines in achievement.[74] When the National Assessment of Educational Progress released its "report card" following the COVID-19 pandemic, the findings were dismal: math and reading scores had dropped significantly, with 9-year-olds showing the largest score decline in reading since 1990, and 13-year-olds posting the largest decline **ever** in math.[75] But 18 months of school closures did not only affect learning. It also contributed to developmental losses and reduced social development, especially among young children; poor emotional well-

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[71] Sarah Mervosh, Claire Cain Miller & Francesca Paris, *What the Data Says About Pandemic School Closures, Four Years Later*, N.Y. Times (Mar. 18, 2024), https://www nytimes.com/2024/03/18/upshot/pandemic-school-closures-data html; Collin Binkley, Associated Press, *School Reopening Debate Tests Biden's Ties with Teachers Unions*, PBS News (Feb. 5, 2021), https://www.pbs.org/newshour/education/school-reopening-debate-tests-bidens-ties-with-teachers-unions.

[72] Sarah Mervosh, Claire Cain Miller & Francesca Paris, *What the Data Says About Pandemic School Closures, Four Years Later*, N.Y. Times (Mar. 18, 2024), https://www nytimes.com/2024/03/18/upshot/pandemic-school-closures-data html.

[73] Press Release, White House, Fact Sheet: President Donald J. Trump is Supporting the Safe Reopening of America's Schools (July 7, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/president-donald-j-trump-is-supporting-the-safe-reopening-of-americas-schools/.

[74] Dan Goldhaber et al., *The Consequences of Remote and Hybrid Instruction During the Pandemic,* CALDER (May 2022), https://caldercenter.org/sites/default/files/CALDER%20Working%20Paper%20267-0522_0.pdf.

[75] Ebony Walton, *Performance Declines in Basic Mathematics and Reading Skills Since the COVID-19 Pandemic Are Evident Across Many Racial/Ethnic Groups*, NAEP Plus (Nov. 9, 2023), https://nces.ed.gov/nationsreportcard/blog/pandemic_performance_declines_across_racial_and_ethnic_groups.aspx.

being, increased stress, feelings of isolation, and poor mental health of both children and parents; as well as significant economic impacts.[76]

The *New York Times* concluded, in November of 2023, that taking 50 million children out of classrooms at the beginning of the pandemic "may prove to be the most damaging disruption in the history of American education," having set back student progress in math and reading **by two decades**, and disproportionately impacting children from low-income backgrounds.[77]

It did not have to be this way. At any point in the 18 months that schools were closed, the CDC could have looked to its peer public health agencies in Europe who had managed to keep schools open and continued in-person learning throughout the same pandemic.

Schools were not superspreader locations. In fact, by April 15, 2020, Denmark eased restrictions to allow children 11 years and younger to return to nurseries and schools.[78] Finland followed soon thereafter.[79] By May of 2020, official data from Denmark and Finland indicated sending children back to schools and daycares did not lead to an increase in coronavirus infections.[80]

In October of 2020, an article published in *Nature* based on worldwide data reported schools were not hot spots for coronavirus infections, and that "[d]espite fears, COVID-19 infections did not surge when schools and day-care centres reopened after pandemic lockdowns eased."[81] Where outbreaks did occur, only a small number of people fell ill. For example, in September of 2020, when Italy saw increased community transmission with more than 2,000 new cases registered each day, as well as a high number of hospital admissions and deaths, only 1,350 SARS-CoV-2 infections (involving 1,059 students, 145 teachers and 146 other school members) were registered at Italian schools, affecting 1,212 Italian schools (1.8 percent) from a total of over 65,000 schools.[82] In Australia, the state of Victoria experienced the most SARS-CoV-2 cases

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[76] Press Release, Joint Econ. Comm. Republicans, What's Next for Schools: Balancing the Costs of School Closures Against COVID-19 Health Risks (Feb. 2, 2021), https://www.jec.senate.gov/public/index.cfm/republicans/2021/2/what-s-next-for-schools-balancing-the-costs-of-school-closures-against-covid-19-health-risks#_ednref1(On file with Committee).

[77] The Editorial Board, *The Startling Evidence on Learning Loss Is In*, N.Y. Times (Nov. 18, 2023), https://www.nytimes.com/2023/11/18/opinion/pandemic-school-learning-loss.html.

[78] *Coronavirus: Denmark Lets Young Children Return to School*, BBC News (Apr. 15, 2020), https://www.bbc.com/news/world-europe-52291326.

[79] *Reopening Schools in Denmark Did Not Worsen Outbreak, Data Shows*, Reuters (May 28, 2020), https://www.reuters.com/article/us-health-coronavirus-denmark-reopening-idUSKBN2341N7/.

[80] *Id.*

[81] Dyani Lewis, *Why Schools Probably Aren't COVID Hotspots*, Nature 587, 17 (Oct. 29, 2020), https://doi.org/10.1038/d41586-020-02973-3.

[82] Danilo Buonsenso et al., *SARS-CoV-2 Infections in Italian Schools: Preliminary Findings After 1 Month of School Opening During the Second Wave of the Pandemic*, Frontiers Pediatrics 8 (2021), https://www.frontiersin.org/journals/pediatrics/articles/10.3389/fped.2020.615894/full.

during two separate waves in 2020.[83] Despite schools remaining partially open, a retrospective study found even when infections occurred in schools, outbreaks were rare, with two-thirds of infections involving a single case in a staff member or student, and over 90 percent of school-related outbreaks involving fewer than 10 people.[84] As clearly demonstrated by the data, it was safe to reopen schools, particularly when community transmission was low. And "even in places where community infections were on the rise, outbreaks in schools were uncommon, particularly when precautions were taken to reduce transmission."[85] The article also noted that children "under 12-14 - are less susceptible to infection than adults" and even if infected, "young children, including those aged 0–5 years, are less likely to pass the virus on to others."[86]

By November of 2020, additional data showed schools did not meaningfully contribute to the spread of COVID-19.[87] COVID infection rates at schools were lower than or similar to the community rate of transmission.[88] Simply put, we would have seen similar infection rates if COVID testing had been conducted at grocery stores, restaurants, or gyms, instead of at schools.

As a result, by the fall of 2020, countries across Europe, including Germany, France, the United Kingdom, and Italy, made concerted efforts to keep schools and childcare centers open despite rising coronavirus cases.[89]

CDC's own *Morbidity and Mortality Weekly Report* (MMWR) published on January 26, 2021, showcased encouraging findings on school reopening's based on the results of a study conducted in 17 rural K-12 schools in Wood County, Wisconsin.[90]

The MMWR is an internal CDC epidemiology digest published weekly by the agency. Articles submitted for publication are not subject to traditional external peer review but are reviewed internally by CDC personnel. Subject matter experts outside of the CDC are not typically invited to participate in the review process, and draft MMWR articles are seldom shared with

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[83] Archana Koirala et al., *Lessons Learnt During the COVID-19 Pandemic: Why Australian Schools Should be Prioritised to Stay Open*, J. Pediatric Child Health 57, 1362–69 (2021), https://www ncbi nlm nih.gov/pmc/articles/PMC8242752/.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] Emily Oster, *Schools Are Not Spreading COVID-19. This New Data Makes the Case.*, Wash. Post (Nov. 20, 2020), https://www.washingtonpost.com/opinions/2020/11/20/covid-19-schools-data-reopening-safety/?arc404=true.
[88] *Id.*
[89] Anya Kamenetz, *Lessons from Europe, Where Cases Are Rising but Schools Are Open*, NPR (Nov. 13, 2020), https://www npr.org/2020/11/13/934153674/lessons-from-europe-where-cases-are-rising-but-schools-are-open.
[90] Amy Falk et al., *COVID-19 Cases and Transmission in 17 K–12 Schools — Wood County, Wisconsin, August 31–November 29, 2020*, CDC (Jan. 29, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e3 htm.

scientists at other HHS agencies, such as the FDA or NIH. Accordingly, the MMWR has been informally nicknamed "the voice of CDC."[91]

The Wisconsin study found that over a 13-week period of in-person learning, 7 of 4,876 students (0.14 percent) and zero of 654 staff were infected with COVID-19 at school.[92] Despite periods of high community transmission rates (up to 40 percent), with proper mitigation strategies, "COVID-19 incidence in schools conducting in-person instruction was 37% lower than that in the surrounding community."[93] The same day, a commentary issued in *JAMA* reported "there has been little evidence that schools have contributed meaningfully to increased community transmission," drawing upon studies conducted at K-12 schools in Mississippi, North Carolina, Wisconsin, in countries across Europe, and in Israel to support its thesis.[94]

Yet, in the Spring of 2021, 24 percent of U.S. schools remained fully remote, and 51 percent were operating under some form of hybrid model.[95] Only 18 percent of schools were teaching fully in-person.[96]

CDC's push for continued school closures exemplifies how the agency ignored the weight of available scientific evidence at the time and upended the lives of millions of American parents and children, in favor of carrying out its political agenda.

Despite all of the evidence to the contrary, the "We Can Do This" Campaign messaging consistently emphasized the possibility of renewed school closures if parents failed to force their children to wear masks, socially distance from friends, or get and stay up to date on their COVID-19 vaccine. The Campaign and the CDC persisted in this messaging after it was apparent schools were not superspreader locations and children were not at high risk of serious illness or death from COVID-19.

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[91] Morbidity & Moratality Wkly. Rep., CDC: Publications, https://www.cdc.gov/mmwr/publications/index.html#:~:text=Often%20called%20%E2%80%9Cthe%20voice%20of,public%20health%20information%20and%20recommendations, (last visited Apr. 24, 2024).
[92] *Id.*
[93] *Id.*
[94] Margaret A. Honein et al., *Data and Policy to Guide Opening Schools Safely to Limit the Spread of SARS-CoV-2 Infection*, JAMA Network (Jan. 26, 2021), https://jamanetwork.com/journals/jama/fullarticle/2775875.
[95] *What's Next for Schools: Balancing the Costs of School Closures Against COVID-19 Health Risks*, U.S. Congress Joint Economic Committee: Republicans (Feb. 2, 2021), https://www.jec.senate.gov/public/index.cfm/republicans/2021/2/what-s-next-for-schools-balancing-the-costs-of-school-closures-against-covid-19-health-risks.
[96] *Id.*

III. March—April 2021: COVID-19 Vaccines Prevent Viral Transmission. Or Do They?

A. CDC Overstates the Effectiveness of the Vaccine at Preventing Infection and Transmission

On March 8, 2021, the CDC issued new guidance stating that people who were fully vaccinated could safely gather with other fully vaccinated people indoors without masks and without social distancing.[97] Moreover, the guidance stated that if you were fully vaccinated and "you've been around someone who has COVID-19, you do not need to stay away from others or get tested unless you have symptoms," suggesting that the CDC believed vaccinated individuals could not spread the virus.[98] However, at the bottom of the guidance was an important caveat that went largely ignored by the Campaign's advertisements:[99]

- **We're still learning** how well COVID-19 vaccines keep people from spreading the disease.
- Early data show that the vaccines may help keep people from spreading COVID-19, but we are learning more as more people get vaccinated.

Given the central role the belief in the efficacy of masks played in the Biden-Harris administration's COVID-19 response, the announcement from President Biden's CDC that fully vaccinated people could safely take off their masks was momentous. The guidance received extensive news coverage with typical articles[100] emphasizing the Biden-Harris administration and the CDC no longer thought masks were a necessary part of daily life:

> In practice, that means fully vaccinated grandparents may visit unvaccinated healthy adult children and healthy grandchildren of the same household without masks or physical distancing. But the visit

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[97] Press Release, Ctrs. for Disease Control & Prevention, CDC Issues First Set of Guidelines on How Fully Vaccinated People Can Visit Safely with Others (Mar. 8, 2021), https://archive.cdc.gov/www.cdc.gov/media/releases/2021/p0308-vaccinated-guidelines html.

[98] Luke Money et al., *What You Can and Can't Do After Getting Fully Vaccinated Against COVID-19*, L.A. Times (Mar. 8, 2021), https://www.latimes.com/california/story/2021-03-08/cdc-post-covid-vaccine-guidelines-what-to-know.

[99] *COVID-19: When You've Been Fully Vaccinated*, CDC, https://web.archive.org/web/20210308164227/https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated html (last updated Mar. 8, 2021).

[100] *See e.g., CDC: Vaccinated People Can Gather Indoors, In Small Groups, Without Masks*, CBS News (Mar. 8, 2021), https://www.cbsnews.com/losangeles/news/cdc-vaccinated-people-may-meet-without-masks/; Mike Stobbe, *CDC Says Many Americans Can Now Go Outside without a Mask*, AP News (Apr. 27, 2021), https://apnews.com/article/cdc-mask-wearing-guidance-d373775ddcf237764c19ff9428b59634; Elizabeth Cohen & John Bonifield, *People Vaccinated Against Covid-19 Can Go without Masks Indoors and Outdoors, CDC Says*, CNN (May 13, 2021), https://www.cnn.com/2021/05/13/health/cdc-mask-guidance-vaccinated/index html; Roni Caryn Rabin, Apoorva Mandavilli & Noah Weiland, *Vaccinated Americans May Go Without Masks in Most Places, Federal Officials Say*, N.Y. Times (May 13, 2021), https://www.nytimes.com/2021/05/13/health/coronavirus-masks-cdc html.

> should be local — the agency still does not recommend travel for any American, vaccinated or not…
>
> "With more and more people getting vaccinated, each day we are starting to turn a corner, and as more Americans are vaccinated, a growing body of evidence now tells us that there are some activities that fully vaccinated people can resume at low risk to themselves," Dr. Rochelle Walensky, the C.D.C. director, said at a White House news conference on Monday.[101]

The guidance, coming less than sixty days after President Biden was inaugurated, also seemed intended to show the President was making good on his campaign pledge to "shut down the virus and not the country" and that by "trusting the science" the pandemic would be over soon.[102] As will be detailed later in this report, the Biden administration would be forced to correct itself in July 2021, and explain to the American people that vaccination did not always prevent infection, nor always stop transmission.[103]

B. "We Can Do This" Campaign Launches First Ads

Within ten days of the CDC issuing its new guidance, the Campaign's first ads began airing on television, radio, and digitally. These ads all emphasized the CDC's position that face masks were effective in combatting the spread of COVID-19, even in light of the new guidance that insinuated masks were no longer necessary if vaccinated. Early ads also focused on promoting vaccination as the way to end social distancing, mask wearing, and to get past the pandemic.

> March 17, 2021: Double Down (Radio) (Audio)[104] (Script)[105]
>
> COVID vaccines are here, and Black physicians and scientists helped to develop them. So, I feel good about getting the vaccine. And with new forms of the virus now spreading, **I know we need to keep up everything we're already doing – masking up, keeping that 6-foot distance, and avoiding crowds**. COVID's

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[101] Roni Caryn Rabin, *Vaccinated Americans May Gather Indoors in Small Groups but Should Still Wear Masks in Public, the C.D.C. Said.,* N.Y. Times (Mar. 8, 2021), https://www nytimes.com/2021/03/08/health/covid-vaccine-cdc-guidelines.html.
[102] Glenn Thrush & Matt Stevens, *5 Policy Issues Where Trump and Biden Diverged at Final Debate,* N.Y. Times (Oct. 23, 2020), https://www nytimes.com/2020/10/23/us/politics/trump-biden-health-care-immigration html.
[103] *See infra* CDC Admits Existence of Breakthrough Cases and Wants Masks Back On, pgs. 31-35.
[104] We Can Do This Campaign, *Double Down*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/archive-double-down-30 (Mar. 18, 2021) (audio recording has been archived).
[105] We Can Do This Campaign, *Double Down*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/sites/default/files/documents/30s_Radio_Double_Down_Final-508c.pdf (Mar. 18, 2021) (transcript of Broadcast Radio has been archived).

been doubly tough on us, so let's double down to take it down. We can do this (emphasis added).

March 18, 2021: On It, (Radio) (Audio) [106] (Script)[107]

Katie: When it comes to protecting our family from COVID, my wife and I…are…ON IT.

Meg: Yeah, and our son loves the outdoors, which is great for all of us...

Katie: ...so, **we're experts at things like social distancing in the park** (emphasis added).

Meg: ...and **you won't see us hanging out indoors with our friends** (emphasis added).

Katie: But now there are new forms of the virus, and they're spreading quickly. So we started wondering, "Are we doing enough?"

Meg: Turns out we are.

Katie: Hey look, **as long as your mask fits well, it still helps protect against the new forms of the virus too** (emphasis added).

Meg: **Yeah, giving people at least six feet of space? That still works** (emphasis added).

Katie: And avoiding crowds cuts our risk of exposure even more. We'll get vaccinated when it's our turn, but now's not the time to let our guard down.

Meg: Not even a bit. It's how we're helping protect our family, and yours too.

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[106] We Can Do This Campaign, *On It*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/archived-on-it-60 (Mar. 18, 2021) (audio recording has been archived).
[107] We Can Do This Campaign, *On It*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/sites/default/files/documents/30s_Radio_Double_Down_Final-508c.pdf (March 18, 2021) (transcript of Broadcast Radio has been archived).

March 18, 2021: Around Here, (Radio) (Audio) [108] (Script)[109]

My family's lived in our town for six generations, so looking out for our neighbors is something that comes naturally to us. So when COVID hit, we did what it took to protect each other. **Now vaccines are here and some folks are easin' up a bit, but that's a big mistake. That's because there are these new forms of the virus and they're spreading quickly. Want to know how to fight 'em? Just do what you've been doing. Got a mask that fits good and snug? Perfect. Giving your neighbors at least six feet of space, avoiding crowds, and not hanging out inside other people's houses? That's all good stuff, and now, it's more important than ever. Look, I'll definitely get my vaccine when it's my turn, but now isn't the time to let your guard or your mask down** (emphasis added).

April 1, 2021: Power (Video) [110]

"This arm has the power to lift us all." Participants in the video then flex the arm where they got a COVID shot. Meanwhile, a background song plays the following lyrics: "I will stand for you; will you stand for me? Everybody deserves to be free. I will lend a hand to you; will you lend a hand to me? Everybody deserves to be free."

April 1, 2021: It's Time (Video) [111]
The video begins with clips showing the impact of COVID era restrictions (e.g., closed businesses, social distancing, empty roads, tired health care workers, hugging through plastic sheets). It then features Dr. Fauci and other individuals getting vaccinated. The caption reads, "In 2020, COVID pushed us all to the brink. Now, we push back." Meanwhile, a background song plays, "it's going to be alright."

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[108] We Can Do This Campaign, *Around Here*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/archived-around-here-60 (Mar. 18, 2021) (audio recording has been archived).
[109] We Can Do This Campaign, *Around Here*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/sites/default/files/documents/60s_Radio_Around_Here_Final-508c.pdf (Mar. 18, 2021) (transcript of Broadcast Radio has been archived).
[110] U.S. Dep't of Health & Hum. Servs., *Power*, YouTube (Apr. 1, 2021), https://www.youtube.com/watch?v=XsVx_PZtigo (content removed by HHS. No longer publicly available as of June 2024).
[111] U.S. Dep't of Health & Hum. Servs., *It's Time*, YouTube (Apr. 1, 2021), https://www.youtube.com/watch?v=6pz--D46R68 (content removed by HHS. No longer publicly available as of June 2024).

C. CDC Director Walensky Doubles Down and then Walks Back

Building on the momentum of the March 8 guidance and demonstrated improvements in infection and mortality data, on March 18, 2021, CDC Director Walensky appeared before the Senate Committee on Health, Education**,** Labor and Pensions to provide an update on the federal response to the pandemic.[112] At the hearing, Dr. Walensky testified on the status of the vaccine rollout and provided an optimistic message for vaccinated individuals:

> About a week ago, we released our first guidance on the first step on what you can do if vaccinated, and that included things like small visits in your home, visits with other vaccinated people unmasked and undistanced, so that you could dine with other vaccinated people in your home. You can also visit with unvaccinated people as long as people in their home don't have risk, high risk of severe disease. **So that is we are still looking at data regarding whether people who are vaccinated can be asymptomatically infected and potentially transmit to other people** (emphasis added)…
>
> We have also released guidance on the fact that you don't have to quarantine if you have been exposed and you are vaccinated. **So the quarantine has gone away with regard to people who are being vaccinated** (emphasis added). We are revisiting what we should do regarding travel for those who are vaccinated, and that should be coming forward soon.[113]

On March 29, 2021, the CDC made public this much-anticipated study as an early release on its MMWR website. The study, titled *Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021*, reported on the results of a three month long observational study of 3,950 healthcare workers.[114] Healthcare workers with two doses of COVID-19 vaccines totaled 2,479 (62.8 percent) of the study cohort, workers with a single dose totaled 477 (12.1 percent) and 994 (25.1 percent) were unvaccinated.[115] Notably, the three clinical trials supporting the vaccines'

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[112] *Examining Our Covid-19 Response: An Update from Federal Officials: Hearing before the Full Committee*, S. Comm. on Health, Educ., Lab. & Pensions, 117th Cong. 61 (2021) (statement of Dr. Rochelle Walensky, Director, U.S. Ctrs. for Disease Control), https://www.congress.gov/event/117th-congress/senate-event/328893/text.
[113] *Id.*
[114] Mark G. Thompson et al., *Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021,* CDC, https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w (last accessed Apr. 2, 2021).
[115] *Id.*

EUA totaled over 90,000 participants, split evenly between vaccinated and unvaccinated participants.[116]

All participating healthcare workers reported no previous laboratory documented SARS-CoV-2 infection. However, given their high-risk of exposure, it seems likely that many had previously contracted COVID-19 without ever having a laboratory confirmed test. Like the EUA clinical trials, the MMWR study found the vaccines were approximately 90 percent effective at preventing infection over three months. The CDC split from the FDA and vaccine manufacturers in concluding that the absence of virus in the weekly PCR tests of vaccinated healthcare workers suggested that the vaccine also reduced viral transmission:

> The findings complement and expand upon these preceding reports by demonstrating that the vaccines can also reduce the risk for infection regardless of COVID-19–associated illness symptom status. **Reducing the risk for transmissible infection, which can occur among persons with asymptomatic infection or among persons several days before symptoms onset, is especially important** among health care personnel, first responders, and other essential and frontline workers given their potential to transmit the virus through frequent close contact with patients and the public (emphasis added).[117]

The results of the CDC study were consistent with the results of the three EUA clinical trials, **but the CDC drew a critical and ultimately erroneous conclusion that the FDA and vaccine manufacturers did not—that COVID vaccines not only prevented illness but also transmission.**

With the release of the study, Dr. Walensky's messaging evolved to include claims that the vaccines would prevent transmission of the virus. In interviews on national news programs, Dr. Walensky discussed a newly released CDC study to support her claim that vaccines prevented

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[116] Press Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; Press Release, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), https://www fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021), https://www fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[117] *Id.*

transmission of the COVID virus.[118] Dr. Walensky's interpretation of the study's results would place the CDC—and the Biden-Harris administration's COVID-19 response—in direct conflict with the FDA's EUA for the vaccines. **In fact, the vaccine manufacturers would have violated federal law if they had made the same claims Dr. Walensky was regularly making regarding the vaccine's effectiveness against transmission, as her statements went beyond the scope of the FDA's EUA.**[119]

"At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person." **FDA EUA for COVID-19 Vaccines (Dec. 11, Dec. 18, 2020, and Feb. 27, 2021)** Source: Press Release, U S Food & Drug Admin , FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec 11, 2020); Press Release, U S Food & Drug Admin , FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec 18, 2020); Press Release, U S Food & Drug Admin , FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb 27, 2021)	"[W]e can kind of almost see the end. We`re vaccinating so very fast, our data from the CDC today suggests, you know, that vaccinated people do not carry the virus, don`t get sick, and that it`s not just in the clinical trials but it`s also in real world data." **CDC Director Rochelle Walenksy (March 29, 2021)** Source: Interview by Rachel Maddow with Rochelle Walensky & Brandt Williams, The Rachel Maddow Show, 30 Rockefeller Plaza, N Y C , N Y (Mar 29, 2021)

Less than two weeks after Dr. Walensky testified before the Senate, and just three days after her interview with Rachel Maddow on the *Rachel Maddow Show*, the CDC was forced to distance itself from Director Walensky's claims in the face of mounting objections from scientists.[120] In a statement to the *New York Times* on April 1, 2021, a CDC spokesperson

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[118] Interview by Rachel Maddow with Rochelle Walensky & Brandt Williams, The Rachel Maddow Show, 30 Rockefeller Plaza, N.Y.C., N.Y. (Mar. 29, 2021), https://www.msnbc.com/transcripts/transcript-rachel-maddow-show-3-29-21-n1262442?utm_content=buffer7fb12&utm_medium=Arianna&utm_source=LinkedIn&utm_campaign=Buffer (underscoring that the CDC's data "suggests. . . that vaccinated people do not carry the virus, don't get sick, and that it's not just the clinical trials but it's also in real world data"); State of the Union, *CDC Director Walensky: "Vaccinated People are Safe"*, CNN (07:15) (May 16, 2021), https://www.cnn.com/videos/politics/2021/05/16/sotu-walensky-full.cnn ("You're protected if you're vaccinated. You are not if you're not vaccinated.").

[119] 21 U.S.C. § 352(a); Press Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine, https://www fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine; Interview by Rachel Maddow with Rochelle Walensky & Brandt Williams, The Rachel Maddow Show, 30 Rockefeller Plaza, N.Y.C., N.Y. (Mar. 29, 2021), https://www msnbc.com/transcripts/transcript-rachel-maddow-show-3-29-21-n1262442?utm_content=buffer7fb12&utm_medium=Arianna&utm_source=LinkedIn&utm_campaign=Buffer.

[120] Joseph Guzman, *CDC Reverses Statement by Director that Vaccinated People are No Longer Contagious*, The Hill (Apr. 2, 2021), https://thehill.com/changing-america/well-being/546234-cdc-reverses-statement-by-director-that-vaccinated-people-are-no/.

explained, "Dr. Walensky spoke broadly during this interview [with Rachel Maddow] . . . It's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. We are continuing to evaluate the evidence."[121]

Despite this uncertainty, at a May 19, 2021, hearing before the Senate Appropriations Committee, Director Walensky reiterated her previously stated position that vaccinated individuals could not transmit the virus to others:

> And (3), something that was not studied in the clinical trials is, can you—if you were to get infection with SARS–CoV–2 and were vaccinated, could you give it to somebody else? Were you silently able to spread it? Those data were not covered in the clinical trials, but now data have emerged again, that have demonstrated, even if you were to get infected during post-vaccination, that you cannot give it to anyone else.[122]

Even with clear disagreement between CDC Director Walensky and CDC scientists, from March 2021 to at least January 2022 when federal vaccine mandates went into effect, the "We Can Do This" Campaign often adopted Director Walensky's message that COVID-19 vaccines stop transmission.[123] The Campaign's messages in the spring, sponsored by HHS and the CDC, were in large part based on the mistaken assumption that the COVID-19 vaccines reduced transmission. The Biden-Harris administration, HHS, and the CDC had, in effect, wagered their credibility with the American people on the issue of COVID-19 vaccinations based on the premise that vaccinated individuals could not transmit COVID-19 to others. This ended up being a critical mistake when, just months later, breakthrough COVID-19 infections in vaccinated people began being widely reported.

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[121] Apoorva Mandavilli, *Can Vaccinated People Spread the Virus? We Don't Know, Scientists Say,* N.Y. Times (Apr. 1, 2021), https://www.nytimes.com/2021/04/01/health/coronavirus-vaccine-walensky.html.

[122] *Review of the Fiscal Year 2022 Budget Blueprint for the Centers for Disease Control and Prevention: Hearing Before the Subcomm. on the Dep't of Labor, Health, & Hum. Servs., & Educ., & Related Agencies of the S. Comm. on Appropriations*, 117th Cong. 15 (2021) https://www.congress.gov/117/chrg/CHRG-117shrg29104940/CHRG-117shrg29104940.pdf.

[123] *See infra* CDC Admits Existence of Breakthrough Cases and Wants Masks Back On, pgs. 31-35.

IV. May—August 2021: On the Heels of Poorly Issued Guidance, CDC Attempts to "Stop the Spread"

A. Vaccines for Teens

On May 10, 2021, the FDA expanded its EUA of the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12-15 years.[124] Two days later, on May 12, the CDC's Advisory Committee on Immunization Practices (ACIP) made its interim recommendation that all 12–15-year-olds get vaccinated.[125] Central to the Campaign's messaging on the need to vaccinate 12–15-year-olds was the premise that vaccination was key to reopening schools in the fall for in-person instruction. The CDC repeatedly issued statements, guidance documents, and other materials stressing that COVID-19 vaccines and booster shots were necessary for school re-openings. The CDC's insistence that schools could only safely reopen when all children were vaccinated (the vast majority of whom were at low risk for severe illness from COVID-19)[126] suggests the Biden-Harris Administration was implementing policies dictated by its political allies in teachers' unions, rather than by the best scientific evidence available at the time.[127]

The implicit threat to close schools, a common theme in many of the Campaign's ads, stemmed from the Biden-Harris administration and Democrat-led local governments who had been reluctant to push schools to reopen because of opposition from teachers' unions. An ad sponsored by HHS and CDC stating that the only way to avoid closing schools was to vaccinate 12-year-olds was clearly intended to scare parents, given that CDC's first school reopening guidance, if implemented, would have "ke[pt] more than 90 percent of schools, including in almost all of the 50 largest counties in the country, from fully reopening."[128]

To reinforce the need for vaccinations as a requirement for in-person learning, the Campaign ads between May and August of 2021 specifically targeted adolescents in the 12-15-year-old age group, likely under the assumption they would pressure their parents into getting them vaccinated. A recurrent theme in Campaign ads targeted towards teens insinuated that vaccines would bring back pre-pandemic life and that only non-vaccinated individuals could get infected.

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[124] Megan Wallace et al., *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12-15 Years--United States, May 2021,* CDC (May 10, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1 htm?s_cid=mm7020e1_w.
[125] *Id.*
[126] *See supra* February 2021: CDC Issues School Re-Opening Guidance Influenced by Teachers' Unions, pgs. 14-19, and *infra* Vaccines and Boosters Approved for Young Children (5-11 Years), pgs. 40-43.
[127] Rachel M. Cohen, *New School Year, Same Old Covid Chaos*, New Republic (Aug. 17, 2021), https://newrepublic.com/article/163287/kids-vaccine-covid-schools-reopening-delta-cdc.
[128] Will Feuer, *CDC's Classroom Guidance Would Keep 90% of Schools at least Partially Closed*, CNBC News (Feb. 18, 2021), https://www.cnbc.com/2021/02/18/cdcs-classroom-guidance-would-keep-90percent-of-schools-at-least-partially-closed html.

The HHS taxpayer-funded Campaign used emotionally manipulative ads to make clear that getting vaccinated was the only way to see friends, hang out, go on dates, have parties, vacation, and have sleepovers. **In the summer of 2024, all HHS Campaign materials available on YouTube were made private and are no longer accessible to the public.**

June 16, 2021: Yes (Video)[129]

"Say yes. Say yes to seeing friends. Yes to hanging out. Yes to vacations. Yes to sleepovers. After a year of saying no. Imagine how good yes is going to feel. Everyone 12 and older is now eligible for COVID vaccines."

June 22, 2021: Party Like It's 2019 (Video)[130]

The video features scenes of nightclubs, concerts, and other events where people are partying. A caption reads: "Get a COVID vaccine. Party like it's 2019."

June 24, 2021: LOLs (Video)[131]

"LOLs [laugh out louds] are better IRL [in real life]. Get a COVID vaccine. Get back out there."

June 24, 2021: Gaming IRL (Video)[132]

The video features scenes of parties, people playing pool, bowling, and engaging in other social activities. The caption reads: "Get a COVID vaccine. Get back out there."

Early ads also mirrored Dr. Walensky's slogan that with the vaccines becoming available, the end of the pandemic—and pandemic restrictions—was in sight.

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[129] U.S. Dep't of Health & Hum. Servs., *Yes*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 16, 2021), https://www.youtube.com/watch?v=ehdCtHOx50g (content removed by HHS. No longer publicly available as of June 2024).
[130] U.S. Dep't of Health & Hum. Servs., *Party Like It's 2019*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 22, 2021), https://www.youtube.com/watch?v=PSyRgozUViM (content removed by HHS. No longer publicly available as of June 2024).
[131] U.S. Dep't of Health & Hum. Servs., *LOLs*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 24, 2021), https://www.youtube.com/watch?v=1T-iAVB7lVs (content removed by HHS. No longer publicly available as of June 2024).
[132] U.S. Dep't of Health & Hum. Servs., *Gaming IRL*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 24, 2021), https://www.youtube.com/watch?v=1T-iAVB7lVs (content removed by HHS. No longer publicly available as of June 2024).

June 24, 2021: Free to Do What You Want (Video)[133]

"Every vaccine is free. So, we can all become mask free. Free to do what we want. We can do this."

June 24, 2021: Get Vaxxed Get Social (Video)[134]

"First, we had to stay home. Then, socially distance. COVID vaccines are free and easier to find. Ya podemos janguear again. Get vaxxed and get social. We can do this."

June 29, 2021: Say "Yes" Again with COVID-19 Vaccines (Video)[135]

"Say yes to dates. Say yes to parties. Say yes to music. Let's do our part to end this pandemic."

Notably, in all of these ads, actors appear unmasked.

As early as June 2021, the Campaign also released ads targeting parents of children six months and older.

June 29, 2021: Get the Facts About Vaccines for Children (Video)[136]

"What will COVID vaccination look like for **children ages 6 months and older**? They'll receive smaller, **child-size doses.** This means they'll get the **best protection** available with doses that are tailored especially for them, and you'll get peace of mind, knowing that you're helping to **keep them safe**."

Ads aired on August 12, 2021, titled "We Can (Back to School)," played upbeat pop music, with faces of happy, smiling, masked and unmasked school-aged children flashing across the screen, as captions read:

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[133] U.S. Dep't of Health & Hum. Servs., *Free to Do What You Want*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 24, 2021), https://www.youtube.com/watch?v=3_fw_R424JI (content removed by HHS. No longer publicly available as of June 2024).
[134] U.S. Dep't of Health & Hum. Servs., *Get Vaxxed Get Social*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 24, 2021), https://www.youtube.com/watch?v=ctxGujDo-pI (content removed by HHS. No longer publicly available as of June 2024).
[135] U.S. Dep't of Health & Hum. Servs., *Say "Yes" Again with COVID-19 Vaccines*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 29, 2021) https://www.youtube.com/watch?v=y8gYF_x9Tuc (content removed by HHS. No longer publicly available as of June 2024).
[136] U.S. Dep't of Health & Hum. Servs., *Get the Facts About Vaccines for Children*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 29, 2021), https://www.youtube.com/watch?v=aFWp--QCuHM (content removed by HHS. No longer publicly available as of June 2024).

> **"Who's ready to go back to school? He is. She is. We are. They are. Kinda. I'm here now. We are all ready. Let's go. Vaccines are highly effective against the delta variant."** We Can (Back to School) (30 Sec) (Video)[137]
>
> A shorter version said: **"COVID vaccines are highly effective against the Delta variant and everyone 12+ is eligible. So, let's set those alarms, load up those backpacks and get off to a great start."** We Can (Back to School) (15 Sec) (Video)[138]

B. CDC Admits Existence of Breakthrough Cases and Wants Masks Back On

On July 3, 2021, the Delta variant became the dominant SARS-CoV-2 variant circulating in the United States.[139] The Delta variant was the first variant to gain widespread circulation with the ability to infect vaccinated people.[140] In the months leading up to the emergence of the Delta variant, CDC and Biden-Harris administration officials stressed that masks were no longer needed for fully vaccinated individuals. The Campaign also ran ads stressing this message.

For example, an ad that started running on July 7, 2021, targeting the Hispanic community, was narrated by a doctor declaring, "**if you are fully vaccinated, you can resume activities without wearing masks or maintaining physical distance**, except where required by local regulations" (emphasis added).[141] A more accurate statement would have noted that vaccinated individuals could be infected with COVID-19 and still transmit it to others, in much the same way as an unvaccinated, mask-wearing person could.

Four months after the CDC's March 8 guidance that fully vaccinated people no longer needed to mask, "large public gatherings"—as described by the CDC—held between July 3-17 of 2021, in Barnstable County, Massachusetts, resulted in a massive COVID-19 outbreak,

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[137] U.S. Department of Health and Human Services, *We Can (Back to School) (30 Sec)*, *Parents and COVID-19 Vaccines Collection*, YouTube (August 12, 2021), https://www.youtube.com/watch?v=hmJzgn2h7F4 (content removed by HHS. No longer publicly available as of June 2024).

[138] U.S. Department of Health and Human Services, *We Can (Back to School) (15 Sec)*, *Parents and COVID-19 Vaccines Collection*, YouTube (August 12, 2021), https://www.youtube.com/watch?v=UFYwVKy8FIY (content removed by HHS. No longer publicly available as of June 2024).

[139] Manohar B. Mutnal et al., Surveillance Genome Sequencing Reveals Multiple SARS-CoV-2 Variants Circulating in Central Texas, USA, With a Predominance of Delta Variant and Review of Vaccine Breakthrough Cases, 94 J. Med. Virol. 937 (2022), https://www ncbi.nlm.nih.gov/pmc/articles/PMC8661622/#:~:text=the%20delta%20(B.-,1.617.,on%20July%207%2C%202021.

[140] Emily Anthes, *The Delta Variant: What Scientists Know*, N.Y. Times (June 22, 2021), https://www nytimes.com/2021/06/22/health/delta-variant-covid.html.

[141] U.S. Dep't of Health & Hum. Servs., *¿Cuánto dura la protección de la vacuna contra el COVID-19?*, *Parents and COVID-19 Vaccines Collection*, YouTube (July 7, 2021), https://www.youtube.com/watch?v=_p6Zxz949TI (content removed by HHS. No longer publicly available as of June 2024).

largely among vaccinated adults.[142] This outbreak caused the CDC to change its masking guidance yet again. While the CDC report describes the circumstances in Barnstable County in July of 2021 as "large public gatherings," the CDC's use of the term failed to capture or reflect the size and intimacy of the crowd, as reflected in an article from *The Atlantic* titled, "Hot Vax Summer Crumbled Before My Eyes."[143] These COVID-19 cases centered around the town of Provincetown, where tens of thousands of visitors arrived to participate in Bear Week from July 10-18, 2021.[144]

On July 27, 2021, based on its data from the Provincetown outbreak, the CDC reversed course and issued guidance that fully vaccinated individuals should continue to wear masks in areas of high transmission.[145] The CDC was criticized for changing its masking guidance without publishing the data on which it was based.[146] The CDC's MMWR report of the outbreak found that among 469 cases which occurred in Massachusetts, 346 cases (74 percent) occurred in **persons who were fully vaccinated**.[147] The CDC called these outbreaks "breakthrough infections." Shortly after, Director Walensky stated that "such transmission occurs on 'rare occasions.'"[148] At the same time, an internal CDC document obtained by *The Washington Post* "estimated that 35,000 vaccinated people **a week** in the United States are having symptomatic breakthrough infections, out of a vaccinated population of more than 162 million" (emphasis added).[149] Walensky's March statements that vaccinated individuals do not carry the virus and do not get sick, plus her July insistence that breakthrough infections occurred on "rare occasions," and the CDC's continued support of masking, damaged the CDC's credibility and undercut the public's trust.[150]

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[142] Catherine M. Brown et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings—Barnstable County, Massachusetts, July 2021*, 70 Morbidity & Mortality Wkly. 1059-1062 (Aug. 6, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w.

[143] Spencer Kornhaber, *Hot Vax Summer Crumbled Before My Eyes,* The Atlantic (Aug. 3, 2021), https://www.theatlantic.com/culture/archive/2021/08/provincetown-delta-variant-hot-vax-summer/619648/.

[144] *Id.*

[145] Ctr. for Disease Control & Prevention, *CDC Museum COVID-19 Timeline*, David J. Sencer CDC Museum: In Association with the Smithsonian Institution, https://www.cdc.gov/museum/timeline/covid19.html (last accessed Oct. 18, 2024).

[146] Carolyn Y. Johnson, *CDC Study Shows Three-Fourths of People Infected in Massachusetts Coronavirus Outbreak Were Vaccinated but Few Required Hospitalization*, Wash. Post. (July 30, 2021), https://www.washingtonpost.com/health/2021/07/30/provincetown-covid-outbreak-vaccinated/.

[147] Catherine M. Brown et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings—Barnstable County, Massachusetts, July 2021*, 70 Morbidity & Mortality Wkly. 1059-1062 (July 1, 2022), https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w.

[148] Carolyn Y. Johnson, *CDC Study Shows Three-Fourths of People Infected in Massachusetts Coronavirus Outbreak Were Vaccinated but Few Required Hospitalization*, Wash. Post. (July 30, 2021), https://www.washingtonpost.com/health/2021/07/30/provincetown-covid-outbreak-vaccinated/.

[149] *Id.*

[150] Interview by Rachel Maddow with Rochelle Walensky & Brandt Williams, The Rachel Maddow Show, 30 Rockefeller Plaza, N.Y.C., N.Y. (Mar. 29, 2021), https://www.msnbc.com/transcripts/transcript-rachel-maddow-

The failure of the CDC and Biden Administration to anticipate and communicate that a new variant may evade vaccine coverage when promoting the COVID-19 vaccines is inexcusable. The CDC has been responsible for administering the annual federal flu shot program for decades. **CDC personnel should—and must—have known that, historically, vaccines inoculating against respiratory viruses are seldom 100 percent effective at stopping transmission, largely due to viral mutation.**[151] The annual flu shot has a typical effectiveness of 40 to 60 percent because of antigenic drift and mutations; SARS-CoV-2 mutates even more rapidly than influenza.[152] Moreover, the CDC, based on its experience with influenza vaccine campaigns, should have had a better understanding of general uptake rates – and thus, that ending the pandemic by convincing 100 percent of the country to take a vaccine is unrealistic – less than 50 percent of all adults in the U.S. get an annual flu shot.[153]

As *The Washington Post* reported, "[c]ritically, the [MMWR] study found that vaccinated individuals carried as much virus in their noses as unvaccinated individuals, strongly suggesting that vaccinated people could spread the virus to others."[154] Still, the CDC resorted to a one-size-fits-all general mask mandate despite the lack of evidence suggesting masks prevent transmission. After running months of ads stressing that universal vaccination would end masking and social distancing, the Campaign now launched new ads telling people to go back to masking and social distancing, even if fully vaccinated. The return of masking damaged any remaining credibility the CDC enjoyed amongst a wide swath of the American people.

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show-3-29-21-n1262442?utm_content=buffer7fb12&utm_medium=Arianna&utm_source=LinkedIn&utm_campaign=Buffer; Carolyn Y. Johnson, CDC Study Shows Three-Fourths of People Infected in Massachusetts Coronavirus Outbreak Were Vaccinated but Few Required Hospitalization, Wash. Post. (July 30, 2021), https://www.washingtonpost.com/health/2021/07/30/provincetown-covid-outbreak-vaccinated/.

[151] Koen B. Pouwels et al., *Effect of Delta Variant on Viral Burden and Vaccine Effectiveness Against New SARS-CoV-2 Infections in the UK*. Nat Med 27, 2127–2135 (2021), https://doi.org/10.1038/s41591-021-01548-7.

[152] Ctr. For Disease Control & Prevention, How Well Do Flu Vaccines Work?, National Ctr. For Immunization & Respiratory Diseases (NCIRD), https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm (last accessed Feb. 8, 2023).

[153] Ctr. For Disease Control & Prevention, Vaccination Trends—Adults, https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults html#:~:text=The%20percent%20of%20the%20population%20reporting%20receipt%20of%20a%20flu,%25%20(23.7%2D25.2) (last accessed May 22, 2024).

[154] Carolyn Y. Johnson, *CDC Study Shows Three-Fourths of People Infected in Massachusetts Coronavirus Outbreak Were Vaccinated but Few Required Hospitalization*, Wash. Post. (July 30, 2021), https://www.washingtonpost.com/health/2021/07/30/provincetown-covid-outbreak-vaccinated/.

July 19, 2021: Two radio ads targeting Native American parents

Double Up Mom (Radio) (Audio)[155] (Script)[156]

"My mom is interesting; she goes to the grocery store and buys two of everything. I ask her, "what's the deal?" She tells me that there is nothing worse than cooking dinner for the family and you need more of something and it's not there. She said she would rather go all-in and double-up to make sure she is covered. I get it.

I am now doing that with the pandemic. I know many people are getting the vaccine, but there are new forms of the virus, and I don't want to take the chance. **Wearing a well-fitted mask, keeping 6 feet apart, and avoiding crowds are my way of doubling-up against the virus.** We need to continue to protect our people and our tribal communities.

Help prevent the spread of the new forms of the virus by continuing to wear a snug mask, keep 6 feet apart when you're around others, and when it's your turn get vaccinated" (emphasis added).

Double Up Dad (Radio) (Audio)[157] (Script)[158]

"My son and I were headed down to the store when he asked me why I always get an extra bag of nuts and an extra water. Well, it's a backup, I tell him. It's doubling-up, so you are covered for later.

He then asks me why I am still avoiding crowded places and wearing my mask since I already got the vaccine. I say son, "it's the double-up effect." It's doing our part and doing what is right, so we are protected. There are new forms of the virus, so we need to double-up to beat them,

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[155] We Can Do This Campaign, *Double Up Mom*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/archived-double-mom (July 19, 2021) (audio recording has been archived).
[156] We Can Do This Campaign, *Double Up Mom*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/sites/default/files/documents/60s_Radio_Double_Up_Mom_Final-508c_0.pdf (July 19, 2021) (transcript of Broadcast Radio has been archived).
[157] We Can Do This Campaign, *Double Up Dad*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/archived-double-dad (July 19, 2021) (audio recording has been archived).
[158] We Can Do This Campaign, *Double Up Dad*, U.S. Dep't of Health & Hum. Servs., https://www.covid.gov/sites/default/files/documents/60s_Radio_Double_Up_Dad_Final-508c_0.pdf (July 19, 2021) (transcript of Broadcast Radio has been archived).

I tell him, "it's for all our people in all our communities." So now, more than ever, we still need to continue to do our part, to keep each other safe from the COVID virus.

Help prevent the spread of the new forms of the virus by continuing to wear masks that fit well, keep 6 feet apart when you're around others, and when it's your turn get vaccinated" (emphasis added).

August 2, 2021: "Let's Get Back To Making History" (Video)[159]

"Honor our past, be influenced by those who came before us and rise to make a difference. It's easier than ever before to be a Modern-Day Warrior. Let's get vaccinated, so we can get back to making history. We can do this!"

August 11, 2021: "Surgeon General Delta Variant Message for Vaccinated People" (Video)[160]

"It is uncommon for vaccinated people to get COVID-19, but some can get and spread it to others. Wearing a mask in public indoor spaces gives everyone extra protection" (emphasis added).

V. September 2021—February 2022: The Biden-Harris Administration Strongarms the American Public, as CDC Targets Young Children

A. The First Boosters

On August 18, 2021, at a White House press briefing, the leaders of the COVID-19 federal response team announced the executive branch's booster rollout plan, as well as their hope that it would stem the rising number of infections, hospitalizations, and deaths caused by the Delta variant. The Biden-Harris response team continued to promote the narrative that the COVID-19 pandemic remained "a pandemic of the unvaccinated," despite the increasing number of breakthrough cases among vaccinated individuals. [161]

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[159] U.S. Dep't of Health & Hum. Servs., *"Let's Get Back To Making History"*, *Parents and COVID-19 Vaccines Collection*, YouTube (Aug. 2, 2021), https://www.youtube.com/watch?v=Ry0KQj5n-tE&list=PLrl7E8KABz1Feb8FvDwlIiPkAhhn-taA7&index=10 (content removed by HHS. No longer publicly available as of June 2024).

[160] U.S. Dep't of Health & Hum. Servs.,*"Surgeon General Delta Variant Message for Vaccinated People"*, *Parents and COVID-19 Vaccines Collection*, YouTube (Aug. 11, 2021), https://www.youtube.com/watch?v=cwsIDNDu5-k (content removed by HHS. No longer publicly available as of June 2024).

[161] Press Release, White House, Press Briefing by White House COVID-19 Response Team and Public Health Officials (Aug. 18, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/18/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-50/.

Surgeon General Vivek Murthy laid out the Biden-Harris administration's plan to offer COVID-19 boosters to "fully vaccinated adults 18 years and older," who "would be eligible for their booster shot eight months after receiving their second dose of the Pfizer or Moderna mRNA vaccines."[162] The booster shot program was set to start the week of September 20, 2021.[163] It is notable the administration did not have a clear answer on the number of booster doses that would be necessary for a person to be considered "fully vaccinated."[164] As time would tell, this would be an evolving number, with COVID booster shots still being encouraged as of the time of this report.

The Surgeon General went on to state:

> I want to be very clear: This plan is pending the FDA conducting an independent evaluation of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and the CDC's Advisory Committee on Immunization Practices issuing booster dose recommendations based on a thorough review of the evidence.[165]

When Shannon Pettypiece, an NBC reporter, asked why the administration was skipping the typical FDA review process for the booster rollout—where FDA first reviews the safety and efficacy of the vaccines and provides approval, following which CDC's ACIP grants its approval—the Surgeon General clarified yet again that the administration would not be skipping the "very important" FDA and ACIP process.[166] Dr. Walensky chimed in to say "we are very much following what ACIP provided."[167]

This would turn out not to be true.

On September 1, 2021, FDA announced it would hold a meeting of its Vaccines and Related Biological Products Advisory Committee on September 17, 2021, to discuss licensing of the Pfizer-BioNTech COVID booster for administration in those 16 years and older.[168] The very same day, FDA announced two of its senior vaccine advisors—Dr. Marion Gruber, the director of the FDA's Office of Vaccines Research and Review (OVRR) at the Center for Biologics

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[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] *Id.*
[167] *Id.*
[168] *FDA In Brief: FDA to Hold Advisory Committee Meeting to Discuss Pfizer-BioNTech's Application for COVID-19 Booster,* U.S. Food & Drug Admin. (Sept. 1, 2021), https://www.fda.gov/news-events/press-announcements/fda-brief-fda-hold-advisory-committee-meeting-discuss-pfizer-biontechs-application-covid-19-booster.

Evaluation and Research (CBER), and her deputy, Dr. Philip Krause—would be resigning.[169] According to reports, Drs. Gruber and Krause had resigned "**in anger over the Biden administration's plan to roll out COVID-19 booster shots before officials had a chance to approve it** (emphasis added)."[170] Dr. Gruber had been at the FDA for over three decades. The abrupt departure of two prominent FDA advisors triggered turmoil at the FDA with the agency "facing a potential mutiny among its staff and outside vaccine advisers, several of whom feel cut out of key decisions and who view the plan to offer boosters to all adults as premature and unnecessary."[171] FDA career scientists were frustrated that the agency was losing its autonomy due to political pressure.

Outside experts also raised objections to the administration's plans. Dr. Paul Offit, a University of Pennsylvania infectious disease expert who sits on FDA's Vaccines and Related Biological Products Advisory Committee, called the booster roll out "the administration's booster plan; it wasn't the FDA's booster plan."[172] He went on to state "[t]he administration has kind of backed themselves up against the wall a little bit here" by encouraging boosters for all.[173]

On September 13, 2021, Drs. Krause and Gruber, along with WHO Chief Scientist Soumya Swaminathan and executive director of the WHO's Health Emergencies Program Michael Ryan writing in the medical journal, *Lancet*, publicly panned the Biden administration's plan to administer booster vaccinations to the general population.[174]

The authors argued:

> Although the benefits of primary COVID-19 vaccination clearly outweigh the risks, there could be risks if boosters are widely introduced too soon, or too frequently, especially with vaccines that can have immune-mediated side-effects (such as myocarditis, which is more common after the second dose of some mRNA vaccines, or Guillain-Barre syndrome, which has been associated with adenovirus-vectored COVID-19 vaccines). If unnecessary boosting causes significant adverse reactions, there could be implications for vaccine acceptance that go beyond COVID-19 vaccines. Thus,

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[169] Ashley Collman, 2 Top FDA Officials Resigned over the Biden Administration's Booster-Shot Plan, Saying It Insisted on the Policy Before the Agency Approved It, Reports Say, Business Insider (Sep. 1, 2021), https://www.businessinsider.com/2-top-fda-officials-resigned-biden-booster-plan-reports-2021-9.
[170] *Id.*
[171] Sarah Owermohle, *Biden's Top-Down Booster Plan Sparks Anger at FDA*, Politico (Aug. 31, 2021), https://www.politico.com/news/2021/08/31/biden-booster-plan-fda-508149.
[172] *Id.*
[173] *Id.*
[174] Philip R Krause et al., Considerations in boosting COVID-19 vaccine immune responses, 398 Lancet 1377-80 (Oct. 9, 2021), https://doi.org/10.1016/S0140-6736(21)02046-8.

widespread boosting should be undertaken only if there is clear evidence that it is appropriate.

….

Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high.

….

The ability of vaccines that present the antigens of earlier phases of the pandemic (rather than variant-specific antigens) to elicit humoral immune responses against currently circulating variants indicates that these variants have not yet evolved to the point at which they are likely to escape the memory immune responses induced by those vaccines. Even without any changes in vaccine efficacy, increasing success in delivering vaccines to large populations will inevitably lead to increasing numbers of breakthrough cases, especially if vaccination leads to behavioural changes in vaccinees.

….

Thus, any decisions about the need for boosting or timing of boosting should be based on careful analyses of adequately controlled clinical or epidemiological data, or both, indicating a persistent and meaningful reduction in severe disease, with a benefit–risk evaluation that considers the number of severe cases that boosting would be expected to prevent, along with evidence about whether a specific boosting regimen is likely to be safe and effective against currently circulating variants. As more information becomes available, it may first provide evidence that boosting is needed in some subpopulations. However, these high-stakes decisions should be based on peer-reviewed and publicly available data and robust international scientific discussion.

The vaccines that are currently available are safe, effective, and save lives. The limited supply of these vaccines will save the most lives

> if made available to people who are at appreciable risk of serious disease and have not yet received any vaccine.[175]

On September 22, 2021, nine days after the *Lancet* article was published, the FDA amended its EUA of the Pfizer vaccine to allow a single booster dose to be administered at least six months after completion of the primary series in the elderly, in individuals at high risk of severe COVID-19, and in individuals aged 18-64 who had completed a primary vaccine series and whose frequent institutional or occupational exposure to the virus put them at high risk of serious complications of COVID-19.[176]

The following day, ACIP approved the use of a single booster dose of the Pfizer vaccine in the elderly and in individuals at high risk of severe COVID-19 infection. However, ACIP voted **against** recommending booster doses in individuals aged 18-64 who had completed a primary vaccine series and who may be exposed to COVID-19 through occupational or institutional settings. [177]

CDC Director Walensky approved ACIP's recommendations to allow the use of booster doses in the elderly and in high-risk individuals. However, in a **highly unusual** move, Director Walensky overruled ACIP and issued her own recommendation allowing booster doses for healthy individuals at risk of occupational COVID-19 infection.[178] Walensky's decision to go against her own agency's advisers surprised not only ACIP members, but also members of her staff and other experts.[179] An ACIP member who voted against recommending boosters for younger individuals with occupational risk stated "the committee was being drawn into an 'emotional situation' and that it needed to focus on the science," which had not supported the use of boosters in younger age groups.[180]

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[175] *Id.*

[176] Press Release, U.S. Food & Drug Admin., FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations (Sept. 22, 2021), https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations.

[177] Sarah Mbaeyi, MD, et al., *The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021,* MMWR Morbidity & Mortality Wkly. Rep. 2021; 70:1545-1552 (Nov. 5, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e2.htm#T1_down.

[178] Sarah Mbaeyi, *The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021,* 70 Morbidity & Mortality Wkly. 1545–1552 (Nov. 5, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e2 htm?s_cid=mm7044e2_w.

[179] Apoorva Mandavilli & Benjamin Mueller, *C.D.C. Chief Overrules Agency Panel and Recommends Pfizer-BioNTech Boosters for Workers at Risk.*, N. Y. Times (Sept. 24, 2021), https://www nytimes.com/2021/09/24/world/covid-boosters-vaccine-cdc-director html (last updated Oct. 21, 2021).

[180] Ken Downey Jr. & Gerard Gallagher, *In 'Scientific Close Call,' CDC Director Adds Booster Recommendation for HCWs*, Healio (Sept. 24, 2021), https://www healio.com/news/infectious-disease/20210924/in-scientific-close-call-cdc-director-adds-booster-recommendation-for-hcws.

Director Walensky's decision to overrule ACIP **appears to only be the second time a CDC director acted contrary to an ACIP recommendation**—the last instance being in 2003 when former CDC Director Julie Gerberding moved forward with broader recommendations for smallpox vaccination in health workers.[181] It seems Walensky's decision to overrule ACIP was propelled entirely by the Biden-Harris administration's boosters for all strategy, as she had "no choice but to align herself" with the FDA's decision to allow healthy adults to receive the booster.[182] On October 20, 2021, ACIP itself reversed course and formally adopted Walensky's recommendation to allow Pfizer vaccine boosters for individuals at risk of occupational COVID-19 infection, superseding its September 23 recommendation.[183]

B. Vaccines and Boosters Approved for Young Children (5-11 Years)

The CDC and the Campaign continuously overstated the risks COVID-19 posed to children, presumably to scare parents into vaccinating their children. They persisted in this messaging despite ever-increasing scientific evidence that the virus posed a minimal risk to children.

As early as the Spring of 2020, researchers were beginning to find that children were at lower risk of severe COVID-19 infection than adults.[184] A Swiss study, first published in December of 2020, found the risk of severe disease and death associated with COVID-19 was "relatively rare" in children and young adults.[185] The study highlighted age-related biochemical and physiological changes that increased the risk of severe infection in adults. In contrast, the study noted children generally had several protective factors that prevented severe illness.[186] These included a stronger innate and adaptive immune response resulting from continued exposure to

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[181] *Id.*; Morning Briefing, *CDC Suggests Continuing Smallpox Vaccination Program Despite Panel's Advice*, KFF Health News (June 11, 2009), https://kffhealthnews.org/morning-breakout/dr00018530/.

[182] Apoorva Mandavilli & Benjamin Mueller, *C.D.C. Chief Overrules Agency Panel and Recommends Pfizer-BioNTech Boosters for Workers at Risk.*, N. Y. Times (Sept. 24, 2021), https://www nytimes.com/2021/09/24/world/covid-boosters-vaccine-cdc-director html (last updated Oct. 21, 2021).

[183] Sarah Mbaeyi et al., *The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021,* MMWR Morbidity & Mortality Wkly. Rep. 2021; 70:1545-1552 (Nov. 5, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e2.htm#T1_down.

[184] Riccardo Castagnoli et al., *Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection in Children and Adolescents: A Systematic Review,* JAMA Pediatrics 174(9):882-889 (Apr. 22, 2020), https://jamanetwork.com/journals/jamapediatrics/article-abstract/2765169; Niccolò Parri et al., *Children with Covid-19 in Pediatric Emergency Departments in Italy*, New England J. Med. (May 1, 2020) 383(2):187-190, https://www nejm.org/doi/full/10.1056/NEJMc2007617#:~:text=By%20March%2025%2C%20Italy%20had,the%20greatest%20number%20of%20deaths.&text=Children%20younger%20than%2018%20years,were%20hospitalized%2C%20and%20none%20died.

[185] Petra Zimmermann & Nigel Curtis, *Why is COVID-19 Less Severe in Children? A Review of the Proposed Mechanisms Underlying the Age-Related Difference in Severity of SARS-CoV-2 Infections*, Archives of Disease in Childhood 106:429-439 (2021), https://adc.bmj.com/content/106/5/429.info.

[186] *Id.*

multiple viruses, and thus, more frequent recurrent and concurrent infections, as well as the protective effects of routine childhood immunizations, which often provide protection beyond their target disease.

An article in *Nature Medicine*, first printed in July 2021, revealed the findings of a review of **all** deaths in England among children and young people under 18 years who had a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test during the first year of the pandemic.[187] The authors concluded that SARS-CoV-2 infection is "rarely fatal in children and young people," with a **99.995 percent survival rate** among those infected.[188] In children who died exclusively from COVID-19 infection, underlying comorbidities, such as complex neurodisabilities, served as a major risk factor.[189] The study also found the risk of death from COVID-19 was lower in younger children than in teenagers, "suggesting a continuum of risk increasing through the life course from infancy to older adult life."[190] Perhaps with a sense of foreboding, the authors stated "[t]he risk of removal of [children and young people] from their normal activities across education and social events might prove **a greater risk** than that of SARS-CoV-2 itself" (emphasis added), urging caution around decision making regarding isolating and vaccinating children.[191]

Despite a growing body of literature indicating the low risk of severe COVID-19 infection, let alone death, in children, the CDC continued to push to vaccinate kids under 18 years—even those as young as 5 years of age. Notably, on October 29, 2021, the FDA granted the EUA for the Pfizer-BioNTech COVID-19 vaccine for children aged 5-11 years old.[192] ACIP followed the EUA almost immediately, making an interim recommendation in favor of universal vaccination on November 2, 2021.[193] The same day, the CDC recommended the vaccine for children 5-11 years old.[194]

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[187] Clare Smith et al., *Deaths in Children and Young People in England after SARS-CoV-2 Infection During the First Pandemic Year*, Nature Med. 28, 185–192 (2022), https://doi.org/10.1038/s41591-021-01578-1.
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] Press Release, U.S. Food & Drug Admin., FDA Authorizes Pfizer-BioNTech Covid-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age (Oct. 29, 2021) https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.
[193] Sarah Mbaeyi et al., *The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021*, MMWR Morbidity & Mortality Wkly. Rep. (Nov. 5, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7045e1 htm.
[194] Media Statement, *CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years,* Ctr. for Disease Control and Prevention (Nov. 2, 2021), https://web.archive.org/web/20211103001055/https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine html.

The CDC's disregard for emerging evidence that contradicted its own preferred policy outcomes demonstrates an insular culture unable—and unwilling—to change course with evolving science.

By November 10, 2021, in line with ACIP's recommendation, the Campaign began airing ads targeting parents of children aged 5-11 years. These ads inaccurately suggested children were at high risk of severe illness or death from COVID-19. Many ads were emotionally manipulative and sought to incite fear by exaggerating the risk of severe illness and death among low-risk populations, such as children. This was especially true of ads that targeted parents. At the same time, the ads played down vaccine associated risks.

> October 5, 2021: Nurse Felicia (Video)[195] [features Felicia, a registered nurse, who is visibly upset]
> "The Delta wave that we're seeing now, people are younger and sicker, and we're intubating and losing people that are my age and younger. People with kids that are my kids' age that are never gonna see their kids graduate. They're never gonna meet their grandkids and then to know that they could have gotten vaccinated, and it could have made a difference."
>
> November 5, 2021: Irreplaceable 5-11 COVID-19 Vaccines (30 Sec) (Video)[196]
> "He's not some statistic. She's more than a headline. He's not someone's agenda. What they are is irreplaceable. Kids 5 and older can now get a COVID vaccine."
>
> November 11, 2021: Our Future 5-11 COVID-19 Vaccines (30 Sec) (Video)[197]
> "Good news for America's future. For future entrepreneurs. And veterinarians. For tomorrow's firefighters, meteorologists, senators, and CEOs. It's their turn. Now everyone 5 and older can get a COVID vaccine." Background song plays: "Little one, you're gonna

[195] U.S. Dep't of Health & Hum. Servs., *Nurse Felicia*, *Parents and COVID-19 Vaccines Collection*, YouTube (Oct. 5, 2021), https://www.youtube.com/watch?v=TT8c12qiXlk (content removed by HHS. No longer publicly available as of June 2024).
[196] U.S. Dep't of Health & Hum. Servs., *Irreplaceable 5-11 COVID-19 Vaccines (30 Sec)*, *Parents and COVID-19 Vaccines Collection*, YouTube (Nov. 5, 2021), https://www.youtube.com/watch?v=MdpNaQ2Pvbo (content removed by HHS. No longer publicly available as of June 2024).
[197] U.S. Dep't of Health & Hum. Servs., *Our Future 5-11 COVID-19 Vaccines (30 Sec)*, *Parents and COVID-19 Vaccines Collection*, YouTube (Nov. 11, 2021), https://www.youtube.com/watch?v=6CQHYWhO7ec (content removed by HHS. No longer publicly available as of June 2024).

grow and then you're gonna go, but I know, yes, I know, you'll be okay."

C. Full Approval Clears the Way for Vaccine Mandates

On August 23, 2021, the FDA granted approval of the Pfizer-BioNTech COVID-19 vaccine for persons 16 years and older.[198] The approval was based on six months of post-vaccination monitoring from the same clinical trial used to issue the original EUA in December of 2019, and concluded "the vaccine was 91% effective in preventing COVID-19 disease."[199] The follow-up included approximately equal number of vaccinated and unvaccinated participants.

While vaccine effectiveness rates were high in the spring of 2021, public health officials did not predict or communicate to the public the possibility of a new variant emerging that would replace the Alpha variant and dramatically reduce the effectiveness of the existing vaccine.[200]

The six-month follow-up visit for participants occurred on March 13, 2021, just weeks before the first wave of the highly transmissible Delta variant of SARS-CoV-2 emerged in April of 2021. The Delta variant would go on to quickly displace the earlier Alpha variant that the COVID-19 vaccines had proven effective against. By mid-June, the Alpha variant would account for only 42 percent of COVID-19 infections, down from 70 percent in late-April.[201]

The Delta variant would become the predominate variant by early summer 2021. All three FDA authorized COVID-19 vaccines would prove less effective against the Delta variant than they had against the earlier Alpha variant. While the vaccines still offered protection against severe illness and death, they were no longer highly effective against COVID-19 infection. One study out

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[198] Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), https://www fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine; *see also Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years:* Kathleen Dooling et al., *Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021,* Morbidity & Mortality Wkly. (MMWR) (Sept. 24, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e2 htm.

[199] Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), https://www fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[200] Baoqi Zeng et al., *Effectiveness of COVID-19 Vaccines Against SARS-CoV-2 Variants of Concern: A Systematic Review and Meta-Analysis*, BMC Medicine 20, 200 (2022), https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02397-y; Mie Agermose Gram et al., *Vaccine Effectiveness Against SARS-CoV-2 Infection or COVID-19 Hospitalization with the Alpha, Delta, or Omicron SARS-CoV-2 Variant: A Nationwide Danish Cohort Study*, PLOS Medicine (2022), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003992; Toon Braeye et al., *Vaccine Effectiveness Against Transmission of Alpha, Delta and Omicron SARS-COV-2-Infection, Belgian Contact Tracing, 2021–2022*, Vaccine 41, 3292-3300 (May 11, 2023), https://www.sciencedirect.com/science/article/pii/S0264410X23003766.

[201] Eleonora Cella et al., *Early Emergence Phase of SARS-CoV-2 Delta Variant in Florida, US,* Viruses at 1, 8, (Apr. 6, 2022), https://www.ncbi nlm nih.gov/pmc/articles/PMC9028683/.

of Israel found Pfizer-BioNTech's vaccine was only 39 percent effective against infection.[202] Other studies found a significant but less dramatic drop in effectiveness against hospitalization—from around 90 percent down to 75-80 percent.[203] Any capacity the vaccines had to prevent transmission of the Alpha variant was lost against the Delta variant.[204]

At the time, there was extensive speculation that vaccine approval was granted, at least in part, to facilitate the imposition of COVID-19 vaccine mandates by federal, state, and local governments, as well as private employers.[205] Regardless of motive, approval was followed closely by vaccine mandates issued by, and at all levels, of government.

On August 25, 2021, Secretary of Defense Lloyd Austin issued a COVID-19 vaccine mandate for military service members.[206] The mandate also required that any recruit going into the armed services be fully vaccinated and boosted.[207] The mandate would result in over 8,300 service members being discharged for refusing to get the vaccine.[208] It remained in place until it was repealed on December 23, 2022 under the Fiscal Year 2023 National Defense Authorization Act,

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[202] Yasemin Nicola Sakay, *Here's How Well COVID-19 Vaccines Work Against the Delta Variant,* Healthline, https://www healthline.com/health-news/heres-how-well-covid-19-vaccines-work-against-the-delta-variant#Vaccines-vs.-Delta-variant (last updated Sept. 15, 2021).

[203] Alexander Tin, *COVID-19 Vaccine Effectiveness in Preventing Hospitalization Drops Among Oldest Americans, But Still Over 80%, CDC Analysis Finds,* CBS News (Aug. 31, 2021), https://www.cbsnews.com/news/covid-19-vaccine-hospitalization-oldest-americans/; Media Release, Johnson & Johnson, Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. (Sept. 21, 2021), https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s.

[204] David W. Eyre et al., *Effect of Covid-19 Vaccination on Transmission of Alpha and Delta Variants*, New England J. Medicine 386, 744-56 (Jan. 5, 2022), https://www nejm.org/doi/10.1056/NEJMoa2116597.

[205] Jillian Kramer, *How Full FDA Approval Could Pave the Way for COVID-19 Vaccine Mandates,* Nat'l Geographic (June 11, 2021), https://www nationalgeographic.com/science/article/how-full-fda-approval-could-pave-the-way-for-covid-19-vaccine-mandates; Aaron Blake, *What the FDA's Full Vaccine Authorization Could Mean for Vaccine Holdouts,* Wash. Post (Aug. 23, 2021), https://www.washingtonpost.com/politics/2021/08/23/what-fdas-full-vaccine-authorization-could-mean-vaccine-holdouts/.

[206] Memorandum, David Vergun, Secretary of Defense Mandates COVID-19 Vaccinations for Service Members, U.S. Dep't of Def. (Apr. 25, 2021), https://www.defense.gov/News/News-Stories/Article/Article/2746111/secretary-of-defense-mandates-covid-19-vaccinations-for-service-members/.

[207] *Id.*; Heather Mongilio, *Military Recruits Required to Sign Statement Acknowledging COVID-19 Vaccine Mandate Before Training,* U.S. Naval Institute News (Dec. 14, 2021), https://news.usni.org/2021/12/14/military-recruits-required-to-sign-statement-acknowledging-covid-19-vaccine-mandate-before-training.

[208] Meghann Myers, *The Fallout of the Military's COVID-19 Vaccine Mandate*, Military Times (Mar. 27, 2023), https://www militarytimes.com/news/your-military/2023/03/27/the-fallout-of-the-militarys-covid-19-vaccine-mandate/#:~:text=In%20addition%20to%20separating%20more,religious%20objection%2C%20or%20medical%20concerns.

at the insistence of Congressional Republicans.[209] Since its repeal, the Department of Defense has made repeated efforts to entice discharged unvaccinated veterans to rejoin.[210]

On September 9, 2021, the Biden-Harris administration announced that a wave of vaccine mandates would be issued in the coming weeks and months as part of the President's "Path out of the Pandemic" plan.[211] The announcement directly contradicted President Biden's campaign pledge not to issue vaccine mandates. When asked during at a December 2020 event before becoming President if he would mandate COVID-19 vaccines, then-President Elect Biden replied:

> No, I don't think it should be mandatory. I wouldn't demand it to be mandatory … But I would do everything in my power—just like I don't think masks have to be made mandatory nationwide—I'll do everything in my power as President of United States to encourage people to do the right thing and, when they do it, demonstrate that it matters.[212]

Nine months later, faced with a surge driven by the Delta variant, the Biden-Harris administration reneged on its pledge and announced, in a nationwide primetime address, that it would impose COVID-19 vaccine mandates. President Biden stated that "in total, the vaccine requirements in my plan will affect about 100 million Americans."[213] He ominously warned unvaccinated Americans or those who had only received a single dose, that "[w]e've been patient, but our patience is wearing thin."[214] The mandates were presented as a way to protect higher-risk vaccinated workers and those too young to be vaccinated from catching COVID-19 spread by unvaccinated individuals.[215]

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[209] Press Release, U.S. Dep't of Def., DOD Rescinds COVID-19 Vaccination Mandate (Jan. 10, 2023), https://www.defense.gov/News/Releases/Release/Article/3264323/#:~:text=Today%20in%20a%20memo%2C%20Secretary,and%20the%20memorandum%20of%20Nov.

[210] Kenneth Niemeyer, *The US Army is Having a Hard Time Recruiting. Now it's Asking Soldiers Dismissed for Refusing the COVID-19 Vaccine to Come Back.*, Business Insider (Nov. 18, 2023), https://www.businessinsider.com/us-army-invites-back-vaccine-refusing-soldiers-amid-recruitment-crisis-2023-11.

[211] Press Release, President Biden, Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

[212] Forbes Breaking News, *FLASHBACK: In Dec. 2020, Biden Says, 'I Wouldn't Demand It Be Mandatory' Regarding COVID-19 Vaccines*, YouTube (Sept. 10, 2021), https://www.youtube.com/watch?v=-LPP3Ca9IoY.

[213] President Biden, *Remarks by President Biden on Fighting the COVID-19 Pandemic*, The White House (Sept. 9, 2021, 5:20 pm.), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

[214] President Biden, "Remarks by President Biden on Fighting the COVID-19 Pandemic," White House (Sept. 9, 2021, 5:20 pm.), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

[215] *Id.* ("We're going to protect vaccinated workers from unvaccinated co-workers. . . . the best way for a parent to protect their child under the age of 12 starts at home. Every parent, every teen sibling, every caregiver around them should be vaccinated.").

At the time of the announcement, over 175 million Americans were vaccinated with about 80 million Americans remaining unvaccinated.[216] The vast majority of unvaccinated individuals were under the age of 50 and at comparatively low risk of severe illness and death.[217] More importantly, at that time, over 85 percent of people over 65 years old had received one dose, and around 78 percent had completed the two shot primary series.[218] Similarly, over 75 percent of people 50-64 years old had received at least one dose.[219] Thus, the age groups at highest risk of severe illness or death were largely already vaccinated by the time the mandates were announced.[220]

On November 4, 2021, the Department of Labor (DOL), through the Occupational Safety and Health Administration (OSHA), announced a nationwide vaccine mandate for all employers with more than 100 employees.[221] This mandate, if it had gone into effect, would have applied to over 80 million workers.[222] To comply, employers had to ensure their workforces were either fully vaccinated or require unvaccinated workers to show a negative test at least once a week.[223] Employers were required to verify the vaccination status of each employee and keep proof of vaccination on hand. Employers who failed to implement the mandate faced fines ranging from $13,653 to $136,532.[224] Unvaccinated employees were to be "removed from the workplace."[225]

On the same day, CMS announced a vaccine mandate for healthcare workers who worked at any provider that accepted Medicare or Medicaid.[226] The CMS mandate was expected to cover

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[216]Administration of Joseph R. Biden, *Remarks on the COVID–19 Response and National Vaccination Efforts*, Govinfo.gov (Sept. 9, 2021), https://www.govinfo.gov/content/pkg/DCPD-202100725/html/DCPD-202100725 htm.
[217] Lindsay M. Monte, *Who Are the Adults Not Vaccinated Against COVID?*, U.S. Census Bureau (Dec. 28, 2021), https://www.census.gov/library/stories/2021/12/who-are-the-adults-not-vaccinated-against-covid.html; *Underlying Conditions and the Higher Risk for Severe COVID-19*, CDC, https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions html#:~:text=Based%20on%20data%20from%20the,in%20those%20ages%2075%E2%80%9384 (last updated June 14, 2024); Sandhya Pruthi et al., *COVID-19: Who's at Higher Risk of Serious Symptoms?*, Mayo Clinic (Apr. 30, 2024), https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-who-is-at-risk/art-20483301.
[218]*U.S. Coronavirus Vaccine Tracker*, USA Facts, https://web.archive.org/web/20210913063941/https://usafacts.org/visualizations/covid-vaccine-tracker-states/ (last updated Sept. 10, 2021).
[219] *Id.*
[220] *Id.*
[221] *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor, Occupational Safety & Health Admin.*, 595 U.S. ___ , ___ (2022), (per curiam) (slip op., at 4), https://www.supremecourt.gov/opinions/21pdf/21a244_hgci.pdf.
[222] *Id.* at 3.
[223] *Id.* at 4.
[224] *Id.*
[225] Mark E. Brossman et al., *OSHA Issues COVID-19 Vaccination and Testing Emergency Temporary Standard,* Schulte Roth & Zabel LLP (Nov. 10, 2021), https://www.srz.com/en/news_and_insights/alerts/osha-issues-covid-19-vaccination-and-testing-emergency-temporary.
[226] Press Release, White House, Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies, (Nov. 4, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/.

76,000 healthcare facilities and more than 17 million healthcare workers.[227] Both the DOL and CMS mandates were to go into effect on January 4, 2022.[228] As a result of this mandate, thousands of healthcare workers were either laid off or chose to resign.[229]

On November 8, 2021, the CDC implemented vaccine requirements for international travelers arriving to the United States. U.S. citizens, lawful permanent residents, and foreign travelers were required to show proof of vaccination at official ports of entry. And, once again, the Biden-Harris administration exempted illegal immigrants entering the country from the mandate it had imposed on U.S. citizens, lawful residents, and legal visitors.[230] Despite simultaneously enforcing this vaccine mandate the CDC would still require vaccinated Americans to present a negative COVID-19 test within 24 hours of departure for U.S.-bound travelers. In fact, this time frame was decreased in advance of the holiday season from the previously allowable 48 hours.[231]

The Biden-Harris administration's vaccine mandates were a flawed policy that increased distrust in the public health enterprise. The mandates were unpopular and further fueled vaccine skepticism, particularly with an American public already showing pandemic fatigue. To make matters worse, the COVID-19 vaccine mandates were based on faulty or outdated assumptions about the COVID-19 pandemic.

For instance, by the time mandates were imposed, the Delta variant was the predominate circulating variant. The three COVID-19 vaccines had been tested against earlier variants circulating in March of 2021. The vaccines were much less effective at preventing infection against the Delta variant.[232] **The risk of a future variant evading vaccine immunity was well**

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[227] *Id.*

[228] COVID Vaccine and Test Requirements for U.S. Entry, NAFSA (May 16, 2023), https://www.nafsa.org/regulatory-information/covid-vaccine-and-test-requirements-us-entry#:~:text=Until%20June%2012%2C%202022%2C%20a,States%20(see%20details%20below).

[229] Dave Muoio, *How Many Employees Have Hospitals Lost to Vaccine Mandates? Here are the Numbers So Far*, Fierce Healthcare (Feb. 22, 2022), https://www.fiercehealthcare.com/hospitals/how-many-employees-have-hospitals-lost-to-vaccine-mandates-numbers-so-far#:~:text=Southcoast%20Health%2C%20a%20Massachusetts%2Dbased,not%20meet%20its%20vaccination%20requirement.

[230] Press Release, Ctr. for Disease Control & Prevention, CDC Issues Orders Operationalizing the President's Safer, More Stringent International Travel System (Oct. 25, 2021), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2021/p1025-International-Travel-System.html.

[231] Gregory A. Wald, *Coming home for the holidays? COVID Testing Requirements for Air Travelers Reduced to One Day Prior to Departure* (Dec. 3, 2021), https://natlawreview.com/article/coming-home-holidays-covid-testing-requirements-air-travelers-reduced-to-one-day.

[232] Yun Lu et al., *Real-World Effectiveness of mRNA COVID-19 Vaccines Among US Nursing Home Residents Aged ≥65 Years in the Pre-Delta and High Delta Periods,* Open Forum Infectious Diseases, 11(3), ofae051 (Jan. 29, 2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10950043/#:~:text=Results,adjusting%20for%20time%20since%20vaccination; Chris Baraniuk, *Covid-19: How Effective Are Vaccines Against the Delta Variant,* BMJ 2021 (Aug. 9, 2021), https://www.bmj.com/content/374/bmj.n1960; Andrew Joseph, *As Delta Spread, Covid-19 Vaccine Effectiveness Against Infection Fell From 90% to 66% in One Key Study,* Stat News (Aug. 24, 2021),

understood by the CDC and other medical experts, but somehow still not adequately communicated to the American public.

Second, the Biden-Harris administration's vaccine mandates were premised on the incorrect idea that the COVID-19 vaccines stopped or significantly reduced transmission. As discussed earlier in this report, the CDC continuously emphasized agency data suggesting that vaccinated individuals do not transmit the virus, a claim that neither the vaccine manufacturers nor the FDA made.[233] As a result, every well-publicized instance of a breakthrough case or superspreader event among vaccinated individuals served to undermine the rationale for the mandate and drastically undermined public trust in the vaccine.

Finally, by the time the Biden-Harris administration issued its COVID-19 vaccine mandates, a majority of Americans had been vaccinated, including an overwhelming majority of those Americans most at risk of severe illness or death. In fact, by the time the DOL and CMS vaccine mandates went into effect on January 4, 2022, the number of vaccinated adult Americans should have resulted in the country achieving, or being close to achieving, herd immunity, based on earlier predictions by federal COVID-19 response leaders. For example, in December of 2020, Dr. Anthony Fauci publicly told Americans that herd immunity would likely be reached once 70 to 80 percent of the population was vaccinated, although he subsequently admitted that estimate was not based on scientific evidence but intended to push people to get vaccinated.[234]

VI. December 2021—June 2022: The U.S. Becomes a Global Outlier in COVID-19 Policy

A. We Can Do This Campaign Ramps Up

At the same time the Biden-Harris administration was enforcing vaccine mandates, the Campaign ramped up its messaging promoting vaccines for all eligible children, including those as young as five. The Campaign began targeting social media influencers, including parent influencers, to join the drumbeat of child vaccine promotion. The Campaign worked with Mom 2.0,[235] a content creation agency, and City Mom Collective,[236] the nation's largest collection of local mom influencers, to push vaccines on children. In partnership with the Campaign and HHS,

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https://www.statnews.com/2021/08/24/as-delta-spread-covid-19-vaccine-effectiveness-against-infection-fell-from-90-to-66-in-one-key-study/.

[233] *See supra* CDC Overstates the Effectiveness of the Vaccine at Preventing Infection and Transmission, pgs. 20-21.

[234] Press Release, CNBC News, CNBC Transcript: Dr. Anthony Fauci Speaks with CNBC's Meg Tirrell Live During the CNBC Healthy Returns Livestream Today (Dec. 16, 2020), https://www.cnbc.com/2020/12/16/cnbc-transcript-dr-anthony-fauci-speaks-with-cnbcs-meg-tirrell-live-during-the-cnbc-healthy-returns-livestream-today html; see also Donald G. McNeil Jr., *How Much Herd Immunity Is Enough?*, N.Y. Times (Dec. 24, 2020), https://www.nytimes.com/2020/12/24/health/herd-immunity-covid-coronavirus html.

[235] *We Can Do This*, Mom 2.0, https://mom2.com/we-can-do-this/ (last visited Dec. 21, 2023).

[236] Elizabeth Baker, *We Can Do This: Where to Get a COVID-19 Vaccine in Your Community*, City Mom Collective (Jan. 21, 2022), https://www momcollective.com/blog/we-can-do-this-where-to-get-a-covid-19-vaccine-in-your-community/.

Mom 2.0 and City Mom Collective promoted sponsored content, such as blogs and vlogs, that parroted CDC talking points. They touted CDC "facts",[237] and easy access to vaccines.

In addition to providing national locations where children could get a COVID-19 vaccine, the blogs and vlogs sought to emotionally persuade parents and adolescents, through misleading statistics, photos, anecdotal stories of personal tragedies, and even monetary incentives. Notably, the Campaign expended taxpayer dollars on celebrities and social media influencers fully knowing, based on internal surveys, that only 8 percent of adults reported seeking out information about COVID-19 from celebrities and social media influencers in a given month.[238]

In an attempt to establish credibility, the CDC and the Campaign used health professionals or "trusted messengers" to promote the COVID-19 vaccine among children. These ads and social media content used voices from **only** those health professionals whose views aligned with CDC recommendations, allowing no room for dissent.

When Fors Marsh survey findings showed "[b]etween 60 percent and 76 percent of parents of unvaccinated children who are under 18 years old [were] concerned about vaccine side effects," the Campaign emphasized interviews with doctors.[239] These "Ask a Doctor" sessions featured a prominent doctor or other health professional in a specific locality who answered a series of common questions around the COVID-19 vaccine.[240] The chosen interviewees voiced opinions strongly aligned with CDC's recommendations for COVID-19 vaccines and booster shots.

In what could be considered browbeating, these health professionals leveraged their titles and academic experiences to present themselves as the authoritative voice. In many cases, instead of engaging in balanced discussion around the benefits and risks associated with vaccinating children, the doctor or health professional provided a one-sided response where they overstated the rate and severity of COVID-19 infections in children, pushed booster shots, and downplayed potential vaccine side effects.[241]

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[237] *See infra* CDC Admits to Overcounting COVID-19 Deaths, pgs. 63-64.
[238] Fors Marsh Group, Current Events Tracker Wave 56 Results, April 1-3, 2022, FMG000811 (on file with Committee).
[239] Fors Marsh Group, Current Events Tracker Wave 52 Results, March 4-6, 2022, FMG000587 (on file with Committee).
[240] U.S. Dep't of Health & Hum. Servs., *Trust: COVID-19 Vaccines - :30*, *Parents and COVID-19 Vaccines Collection*, YouTube (Mar. 18, 2022), https://www.youtube.com/watch?v=0gCnc2Ufqu8&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR (content removed by HHS. No longer publicly available as of June 2024).
[241] Guy Witberg et al., *Myocarditis after Covid-19 Vaccination in a Large Health Care Organization*, 385 New Eng. J. Med. 2132, 2132-39 (2021), https://www.nejm.org/doi/full/10.1056/NEJMoa2110737; İzzettin Toktaş et al., *Examining the Effect of COVID-19 Vaccines on the Menstrual Cycle: A Study from Turkey*, 120 Medicine e36638 (2023), https://journals.lww.com/md-journal/fulltext/2023/12150/examining_the_effect_of_covid_19_vaccines_on_the.52.aspx; Trupti Pandit et al., *Uncommon Side Effects of COVID-19 Vaccination in the Pediatric Population*, 14 Cureus e30276 (2022),

Tis' The Season | YouTube Vlog (12.23.21)[242]
A mom asks her son on video what it meant for him to get the COVID-19 vaccine. The son responds, "It means I am doing a good thing for the world…progressing in stopping this horrible virus."

"I hope it's helpful to you guys to see us getting it done and seeing that we're okay and you know we did it. I hope that helps people see that it is safe and that it is effective."

"Having [my kids] back in school in-person is so important to me, and for that to continue, the vaccination rates have to go up."

"**I will continue to listen to the health professionals in my life and I will continue ... believing in science because it's brought us so many good things and saved us from so many things** (emphasis added)."

Why I Vaccinated My Kids Against COVID-19 (01.2022)[243]
"**And what I believe to my core is that science can be trusted** (emphasis added)."

"**Data and science don't lie. I feel more informed and confident about this vaccine than I ever have about any other vaccine I have given my children** (emphasis added)."

"I didn't realize the weight of fear I was carrying, sending them to school each day without the protection of a vaccine. But I now send them to school with a peace of mind I didn't have at the start of the school year. They are safer now because they are vaccinated, and I am so grateful."

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https://www.cureus.com/articles/119448-uncommon-side-effects-of-covid-19-vaccination-in-the-pediatric-population#!/; Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, N. Y. Times (Anne R. Bass et al. eds., 2024), https://www nytimes.com/2024/05/03/health/covid-vaccines-side-effects html; Nat'l Academies Sciences et al., *Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration* 13-14 (2024), https://nap nationalacademies.org/catalog/27746/evidence-review-of-the-adverse-effects-of-covid-19-vaccination-and-intramuscular-vaccine-administration.

[242] ItsJustKelli, *Tis' The Season - A Vlog*, YouTube (Dec. 23, 2021), https://www.youtube.com/watch?v=NS2Ha1keWyU.

[243] Jessica N Turner, *Why I Vaccinated My Kids Against COVID-19*, Jessica N. Turner: The Mom Creative (Jan. 5, 2022), https://jessicanturner.com/2022/01/why-i-vaccinated-my-kids-against-covid-19.html.

"If you are not vaccinated – no matter your age – you are at risk of getting sick, and yes, even dying. Since the beginning of the pandemic, more than 1,000 children have died from COVID."

It must be noted, when this blog was published in January 2022, CDC data showed there were 811 total "deaths involving COVID-19" for those aged 0-17.[244]

1 in 5 new COVID cases have been in kids (Video) (1.4.22) [245]
"Protect your kids… up to one in five new cases have been in kids. They are just as likely to get covid as adults"

Extra Layer (Video) (1.6.22)[246]
This ad emphasized the importance of the vaccine booster for those 12 years of age and older, the safety and effectiveness of the vaccine in children, and highlighted HHS's claims of booster's effectiveness against the then-circulating Omicron variant.

Mommy's Baby (Video) (1.7.22) [targeting Native American parents][247]
"Children are sacred. Protecting our children 5 and older from severe illness, hospitalization, and even death from COVID means getting them vaccinated."

We CAN Do This: It's Our Children's Turn | Blog post (1.13.22)[248]
"Fun (and completely unexpected!) fact: CVS at Target gives credits at each COVID vaccination and for every 10 credits you earn a $5 gift certificate to spend in store. Our kids got free stuff just for getting vaccinated. Win-win!"

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[244] Cntr. For Disease Control & Prevention, Nat'l Cntr. For Statistics, Nat'l Vital Health Statistics Sys., Provisional COVID-19 Death Counts by Wk., https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm (last visited Apr. 25, 2024).
[245] U.S. Dep't of Health & Hum. Servs., *1 in 5 new COVID Cases Have Been in Kids*, *Parents and COVID-19 Vaccines Collection*, YouTube (Jan. 4, 2022), https://www.youtube.com/watch?v=p9xuKRKULg4 (content removed by HHS. No longer publicly available as of June 2024).
[246] U.S. Dep't of Health & Hum. Servs., *Extra Layer*, *Parents and COVID-19 Vaccines Collection*, YouTube (Jan. 6, 2022), https://www.youtube.com/watch?v=DgXJknayf9w (content removed by HHS. No longer publicly available as of June 2024).
[247] U.S. Dep't of Health & Hum. Servs., *Mommy's Baby*, *Parents and COVID-19 Vaccines Collection*, YouTube (Jan. 7, 2022), https://www.youtube.com/watch?v=SV2jOr1m-W4 (content removed by HHS. No longer publicly available as of June 2024).
[248] *We CAN Do This: It's Our Children's Turn*, Birmingham Mom Collective (Jan. 13, 2022), https://birminghammomcollective.com/health-and-wellness/we-can-do-this-its-our-childrens-turn/.

> "Neither [child] cried or tensed up, and they both knew they would get their $5 prize once it was over. They got some superhero stickers from the pharmacist and happily raced once again to the dollar spot."
>
> Columbus: We Can Do This!! | Blog post (1.16.22)[249]
> "My dad had his first COVID vaccine, and while on a ventilator, he communicated in writing to the hospital staff his concern that he wouldn't be out of the hospital in time to get his second dose… his worry about missing his second dose of the vaccine became a reality because he didn't make it out of the hospital alive."
>
> "Even though my mom had lost her husband of 51 years just days earlier, she made it a priority to go and get her second dose. I was proud of her determination, even during her time of grieving."
>
> "My dad's last text message to me urged me to get my vaccine. So, when I was eligible, I proudly walked … to receive my shot."
>
> The Extra Mile (Video) (1.18.22)[250]
> "Every time they go out, you make sure they are super protected. The thickest coat. The toughest gear. The best helmet. You always go the extra mile to protect them. Now is the time to get them vaccinated because **COVID is a greater risk to your children than any potential side effects from the vaccine** (emphasis added)."

The Campaign made these assertions in January 2022, merely **two months** after the vaccine had received EUA authorization for use in children 5-11 years old.

> We Can Do This: Where to Get a COVID-19 Vaccine in Your Community (Blog post) (1.21.22)[251]
> "Make your vaccine appointment an event for your kids! **Explain to them that getting a COVID vaccine is the best thing they can do to help stop the spread of the disease in your community** as well as protect themselves. Tell them that getting vaccinated is something

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[249] Amy Onifer, *Columbus: We Can Do This!!*, Columbus Mom (Jan. 16, 2022), https://columbus momcollective.com/health-wellness/columbus-we-can-do-this/.
[250] U.S. Dep't of Health & Hum. Servs., *The Extra Mile*, *Parents and COVID-19 Vaccines Collection*, YouTube (Jan. 18, 2022), https://www.youtube.com/watch?v=P5p0miUNHl0 (content removed by HHS. No longer publicly available as of June 2024).
[251] Elizabeth Baker, *We Can Do This: Where to Get a COVID-19 Vaccine in Your Community*, City Mom Collective (Jan. 21, 2022), https://www momcollective.com/blog/we-can-do-this-where-to-get-a-covid-19-vaccine-in-your-community/.

they get to do, rather than have to do. Let them know that this is also a great way for them to be able to participate in more events, sports activities, and get-togethers with friends."

"**After they get their vaccines, take selfies, go for ice cream, or plan a family movie night—anything to make the experience special and memorable.** Celebrate science and that we now have a tool helping us get back to normal! Our kids have so many disappointing memories from the pandemic; let's make getting COVID vaccines a happy, fun one! (emphasis added)."

COVID-19: A Parent's Story – Tamra (video) (3.10.22)[252]
"I'm Tamra, and I lost my son Tyler to COVID in 2021. It's such a senseless tragedy. Kids that age just think they're invincible, and nothing is ever going to happen to them. That's not true of this COVID. It can be very serious. Bad things happen, even to young people. They are not invincible, and it's such an easy solution to just go get a simple vaccine."

Trust: COVID-19 Vaccines (video) (3.18.22)[253]
"Wondering if the COVID vaccine is right for your child? If you can trust it? Well, I represent over 100,000 family doctors. I represent over 4.3 million registered nurses. Nearly 67,000 pediatricians. And **we all agree on this.** . . . You can trust the COVID vaccine for yourself, or your kids, or your grandkids. I do. I do. I do. **I mean it from the heart** (emphasis added)."

While the Campaign was promoting content encouraging eligible children over the age of five to get vaccinated, the Campaign started priming parents in anticipation of FDA authorization of vaccines for children younger than five. In addition to local parent influencers, the Campaign recruited celebrity moms such as America Ferrera and Kelly Rowland, to help promote vaccination for younger children, particularly 2-4-year-olds, for whom the risk of severe illness and death from COVID-19 are negligible.[254] In each instance, the influencer was chosen to target a specific demographic (e.g., African Americans, Latinos, Asian Americans, Native Hawaiians, and Pacific

[252] U.S. Department of Health and Human Services, *COVID-19: A Parent's Story – Tamra*, *Parents and COVID-19 Vaccines Collection*, YouTube (Mar. 10, 2022), https://www.youtube.com/watch?v=yck2XgaCBEY&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=17 (content removed by HHS. No longer publicly available as of June 2024).
[253] U.S. Department of Health and Human Services, *Trust: COVID-19 Vaccines*, *Parents and COVID-19 Vaccines Collection*, YouTube (Mar. 18, 2022), https://www.youtube.com/watch?v=0gCnc2Ufqu8&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=13 (content removed by HHS. No longer publicly available as of June 2024).
[254] Fors Marsh Group, Advancing vaccINTENT, FMG000550 (Dec. 30, 2021) (on file with Committee).

Islanders). At a time when Americans were looking for assurances, quality information, and scientific rigor, CDC and HHS, through the Campaign, chose to hire Hollywood spokespeople to perpetuate an influence campaign that was not rooted in fact.

> A Parent's Perspective on COVID-19 Vaccines. Kelly Rowland in conversation with Jessica Turner from Mom 2.0. [#WeCanDoThis #Ad Paid for by the U.S. Department of Health and Human Services][255]
>
> *Who did you talk to when making the choice to vaccinate your son?*
>
> "It was really from my godfather. **He's a doctor** and he has read up on everything. And it was very simple for him. He was just like 'get my baby vaccinated.' **It was not like, not a thought at all**" (emphasis added).
>
> She continued,
>
> "He just wanted him to feel safer. **He was like, 'he's going to have this sense of like, being a kid again and a sense of normalcy.'** Again, that really meant a lot to him, and that means a lot to me as well. But that was a main thing for him. He's just like there's so many other things, you know, that can really affect our kids that we probably do by accident every day. **He was like, 'this vaccine is going to give him a sense of freedom again'**" (emphasis added).
>
> On Instagram, Rowland captioned her post[256],
>
> "I'm so thankful to talk to other moms and experts about COVID vaccines. I feel like this comes up on every phone call I have, including one with my godfather, who is a doctor—he just said, "get my baby vaccinated–**this vaccine is going to give him a sense of freedom again**." We are all in this together. **#WeCanDoThis #Ad @HHSgov**" (emphasis added).

[255] mom2summit, *A Parent's Perspective on COVID-19 Vaccines with Kelly Rowland in Conversation with Jessica Turner.*, YouTube (Dec. 16, 2021), https://www.youtube.com/watch?app=desktop&v=rxVSPg2DA80.
[256] Kelly Rowland (@kellyrowland), Instagram (Dec. 17, 2021), https://www.instagram.com/reel/CXmGK2sA_-4/?utm_source=ig_embed&utm_campaign=loading.

Building Vaccine Confidence with Parents (video) [Interview with actress America Ferrera] (4.28.22)[257] The video caption reads, "As kids under 5 years old get closer to being eligible for a COVID vaccine, parents everywhere are looking for accurate information and reassurance. America Ferrera talks about her experience preparing her kids for the vaccine and what has helped her feel confident in the vaccination plan for her family."

Ms. Ferrera then makes the following statements during the interview:

"I trust my pediatrician and **I also trust science** and I trust the process that we have to approve vaccinations for children (emphasis added)."

"I can't wait for the feeling of knowing that **my children have a layer of protection that they didn't previously have**. And I feel so grateful that I have that opportunity to make that choice for my child (emphasis added)."

In the spring and summer of 2022, Mom 2.0 and City Mom Collective, conducted a series of interviews with doctors and health professionals, who were willing to promote the HHS narrative surrounding the importance of COVID vaccines for children.

Dr. Sanjeev Jain Answers Your COVID-19 Questions with San Francisco Bay Area Moms | Blog post, Facebook Interview (5.3.22)[258]

"**COVID is a greater threat to your kids than any potential risk from vaccine side effects** (emphasis added)."

"Extremely rare cases of myocarditis have been seen after vaccination in kids 12-17, but the risk of myocarditis is much higher from COVID than from the vaccine."

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[257] U.S. Department of Health and Human Services, *Building Vaccine Confidence with Parents*, *Parents and COVID-19 Vaccines Collection*, YouTube (Mar. 28, 2022), https://www.youtube.com/watch?v=_Vj7rpK8Kjo&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=7 (content removed by HHS. No longer publicly available as of June 2024).

[258] Pauline Li, *Dr. Sanjeev Jain Answers Your COVID-19 Questions with San Francisco Bay Area Moms*, San Francisco Bay Area Moms (May 3, 2022), https://sanfranciscomoms.com/mom-life/dr-sanjeev-jain-answers-audience-covid-19-questions-with-san-francisco-bay-area-moms/.

"We can't predict how COVID will affect your child but we know children are four times more likely to be hospitalized from COVID if they live in a state with low vaccination rates compared to states with high vaccination rates. The best way to protect your child and others is not to roll the dice on what will happen if they get infected. Vaccines can help protect your child from getting seriously sick or needing hospital care, even if they do get COVID."

Your Vaccine Questions Answered by an Expert | Blog post, Facebook interview (5.11.22)[259]
Q&A with Dr. Jaime E. Fergie, Director of Pediatric Infectious Diseases and Hospital Epidemiologist at Driscoll Children's Hospital.

"**But I reassure parents, they should not be concerned about anything that's going to happen later on down the road. The real problem is getting COVID. That's a real problem. That's where you really get in trouble. That's what's gonna get you to the hospital Intensive Care Unit. That is what is going to give you the inflammation on the heart and the other things**. (emphasis added)."

Interview on COVID-19 Vaccines for Kids With Pediatrician Dr. Smith | Blog post, Facebook Interview (5.16.22)[260]
Q&A with Interview with pediatrician Dr. Alyssa Smith of Pediatric Associates of Hampton and Portsmouth.

"So I personally would not recommend holding off on booster, I would go ahead and get it as soon as your child is eligible, because we simply don't know when the next wave is going to come."

"There has been no vaccine to date that has had side effects beyond a few weeks after a vaccination. So, there isn't any precedent for a vaccine having side effects like years down the road. And it's not really to be expected with the COVID-19 vaccine either."

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[259] *Your Vaccine Questions Answered by an Expert*, Phoenix Moms (May 11, 2022), https://phoenix.momcollective.com/your-vaccine-questions-answered-by-an-expert/.
[260] Allison Dudas, *Interview on COVID-19 Vaccines for Kids With Pediatrician Dr. Smith*, Seacoast Moms (May 16, 2022), https://theseacoastmoms.com/health-wellness/interview-on-covid-19-vaccines-for-kids-with-pediatrician-dr-smith/.

How to Make Empowered Decisions About Children's Health and Safety[261] | Blog (6.9.22)

"[My daughter getting the vaccine] already heard me tell dozens of stories, time and again, about growing up in the slum and losing childhood friends to preventable diseases . . . . We had also recently lost my cousin to COVID-19 and maybe he'd still be with us if he had the opportunity to be vaccinated."

"There is no way to know how COVID will affect your child, but COVID is a greater threat to your child than any potential risk or temporary side effects of the vaccine."

"As positive moms, we find answers in science-based facts, not in fake news or fiction."

¿PORQUÉ HA SIDO IMPORTANTE PARA NOSOTROS VACUNARNOS? (Why Has It Been Important For Us To Get Vaccinated) | Blog post—Spanish (6.9.22)[262]

"Disclaimer: This is a campaign in collaboration with Thomas Jefferson University and NORC at the University of Chicago as part of a Pfizer-funded research study."

"It is proven that the vaccines are 95% effective in preventing hospitalizations and deaths due to COVID-19."

"In 2021 my children received their vaccines, they were not in pain, and they returned to their activities that same day. As if nothing had happened."

"We are very proud of them, and we were worried that more than 14 million children have had COVID but at the same time it fills us with peace of mind to know. The Pfizer vaccine has been shown to be safe and effective in children 5 years and older."

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[261] Elayna Fernandez, *How to Make Empowered Decisions About Children's Health and Safety*, Positive MOM, https://www.thepositivemom.com/childrens-health-and-safety (last updated June 9, 2022).
[262] Rory Lassanske, *¿Porqué Ha Sido Importante Para Nosotros Vacunarnos?* (June 9, 2022), https://www.mamacontemporanea.com/porque-ha-sido-importante-para-nosotros-vacunarnos/ (translated from Spanish to English with Google Translate).

"Why do we get vaccinated against COVID-19? Because we want to continue visiting family members and friends at high risk, protect myself and our community and be part of the solution to end the pandemic."

"May what we are experiencing make us better people, more empathetic and tolerant beings with our environment. I do not think we will return to what we were before, nor will we be the same again, the virus has changed us."

"Getting vaccinated will reduce the chances of others getting sick. Let's continue taking care of ourselves!"

June 15, 2022 Dr. Kristina Bryant Answers Columbus Mom Readers' COVID-19 Vaccine Questions[263] | Columbus Mom—Blog post, Facebook Interview

Q&A with Dr. Kristina Bryant, a pediatric infectious disease doctor at Norton Children's Hospital.

[S]everal parents asked, if my child has already had COVID, why do they still need to be vaccinated? Doesn't getting COVID give kids natural immunity that works as well as the vaccine? How would you answer that question?

"Kids who do develop natural COVID-19 infection do develop some immunity. That immunity wanes over time. We also know that being infected with one variant doesn't necessarily guarantee that you're not going to be infected with the next variant that comes down the line. So getting a vaccine after COVID reduces the risk. In some studies, by half that, you'll go on to get COVID again."

Do you have any advice for parents who have concerns about potential long-term side effects of the COVID-19 vaccines with children?

[263] Amy Onifer, *Dr. Kristina Bryant Answers Columbus Mom Readers' COVID-19 Vaccine Questions*, Columbus Mom (June 15, 2022), https://columbus.momcollective.com/health-wellness/dr-kristina-bryant-answers-columbus-mom-readers-covid-19-vaccine-questions/.

"What I can tell parents is that all of our vaccines that are available for kids right now have undergone a really rigorous process of evaluating for both safety and to make sure that they work well. And so we know that the COVID vaccines that we have for kids right now are safe. They're not associated with any long-term health effects. Now, by contrast, we know that COVID infection IS potentially associated with long-term health consequences in children. Much, much safer to get the vaccine."

So how well are the COVID-19 vaccines working against the variants?

"From the beginning of the pandemic, people who are vaccinated are less likely than those who aren't vaccinated, to be infected, to develop symptoms, to need to be admitted to the hospital, to develop severe disease, or to die from COVID. Some parents may be shocked to know that kids can die from COVID-19. Sure, the vaccine doesn't prevent all infections, but it does prevent severe disease. And that's great news."

Why should my child get a COVID vaccine? If children are already at a lower risk for severe illness from COVID? You've sort of answered this before. But can you touch on that point again?

"Low risk doesn't mean no risk. And while many kids develop mild or asymptomatic disease, not all kids do. Some kids will need to be admitted to the hospital. So a vaccine reduces the risk of severe disease and reduces the risk of multi-system inflammatory syndrome. And we know in adults, vaccine reduces the risk of long COVID, which is important."

June 16, 2022 Questions about the COVID-19 Vaccine for Kids Answered by Dr. Costello[264] | Vermont Moms—Blog post, Facebook interview

Q&A with Dr. Leah Costello from Timber Lane Pediatrics

[264] Jemima Talbot, *Questions about the COVID-19 Vaccine for Kids Answered by Dr. Costello*, Vermont Moms (June 16, 2022), https://vermontmoms.com/questions-about-the-covid-19-vaccine-for-kids-answered-by-dr-costello/.

How well are COVID vaccines working against different COVID variants?

"When we compare the side effects of the vaccine to the effects of the illness, we see that the COVID vaccine really remains quite safe."

"The potential risks of the vaccine are low, but the potential risks from getting COVID in an unvaccinated child are higher. Anything we can do to protect a kid that is safe, we're going to recommend and encourage."

"When we look at how many millions of children have been vaccinated against COVID we see that we have not had any safety signals saying that there is a concern about the safety of the COVID vaccine. **We <u>have</u> seen reports and reports and reports of kids getting quite ill with COVID** (emphasis added)."

"As a pediatrician, trying to promote the health of my patients, my community, and my own family, I say that the benefits of the COVID vaccine to reduce the risk of a rare complication far outweigh the risks of the vaccine."

"We vaccinate because we have trust in the science and the safety of our vaccines."

"I trust in the science, I trust in the safety, I trust in the process around vaccines, and I would never recommend anything for you that I wouldn't do for myself."

Do you have any advice for parents who have concerns about the potential long-term side effects of COVID vaccines in children?

"The reason that we feel so confident answering no is **there is just no plausible reason for the COVID vaccine or any vaccine to cause long-term consequences or late-onset consequences**. (emphasis added)."

"Because the vaccine breaks down so quickly in our body, it's just not scientifically plausible for vaccines to have late-onset or long-term side effects."

"I take great comfort in the fact that we've given millions and millions of vaccines to kids ages five and up, and have had no reports of unexpected or unintended new side effects."

If my kid has already had COVID, why do they need to be vaccinated because doesn't having COVID give a natural immunity that works just as well as a vaccine?

"Unfortunately, COVID infection doesn't work quite as well as the vaccine."

"We don't know what's coming. We don't know what's around the corner. If you remember in December, Omicron, popped up pretty quickly and really changed things here in Vermont schools and childcare centers. Could a new variant be circulating and pop up at any point? Yes, that is a potential and something that we've learned from. Being up to date on vaccines and boosters will allow some protection for that unknown around the corner. Keeping in mind the speed at which Omicron came through our community we need to be aware that it takes several weeks to be fully vaccinated. If your child has not been vaccinated yet, you get one vaccine, then you get another one three weeks later, and then wait another two weeks and you're considered fully vaccinated. So that's a five-week period to be fully vaccinated. Omicron came upon us much faster than that. Having your child vaccinated ahead of time, ahead of those unknowns that are coming, is the best way to provide protection to them."

Why would a child need a COVID vaccine when survival rates are high?

"We do know that the COVID vaccine can reduce the risk of getting COVID, albeit not as well as we initially hoped. But it can reduce the risk of getting COVID and it can significantly reduce the risk of hospitalization and death. Across the United States, thousands of kids were hospitalized in a week in January. Yes, many, many of

> them went home without complications, but they were still hospitalized. And that's risky and that's not something you want your child to go through."
>
> "Anything that pediatricians can do that is safe and effective at helping reduce risks we want to offer to our families. We want to encourage our families and our communities to consider those options. And that option right now is the COVID vaccine."
>
> "We don't know who could get sick and we don't know who could get hospitalized or have prolonged symptoms. Taking a vaccine that has a relatively low risk of side effects and that has been given to millions and millions of children without complications is something that we want to be continuing to offer to kids and their families."
>
> "Kids are not supposed to die. That is absolutely not something that should be happening. If we can do anything to prevent even the smallest number of kids' deaths, and if it is safe and effective, we should do it. **Because kids are not supposed to die and kids have died from this illness . . . If you have anything in your power to prevent that, even if it's not your child, if it's just in your community- vaccines are the way that we keep not only our own family but also our community healthy. We all live in this community. We are all responsible for each other** (emphasis added)."
>
> "Pediatricians are at the forefront of vaccine administration. We give vaccines all day long. Not just COVID vaccines, but all vaccines, all day long, every day. I've been doing that since I left residency in 2010. And before that, during residency as well. Every day that I work, I give vaccines, and I think they're really safe. And they're really effective. They're one of the best public health measures that we have in our bucket of tools. Next to clean drinking water, vaccines have saved the largest number of lives."

By the time these ads were aired or posted between October of 2021 and June of 2022, scientific evidence indicated that the risk of severe illness and death posed by COVID-19 to healthy children and young adults was low and getting lower.[265] A United Kingdom study

[265] *See supra* Vaccines and Boosters Approved for Young Children (5-11 Years), pgs. 40-43.

published in *JAMA Pediatrics*, which examined pediatric hospitalizations for COVID-19 or pediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS) among children and adolescents aged 0-17 years between February 1, 2020 and January 31, 2022, found the risk of severe illness associated with COVID-19 infection among children and adolescents was low and **decreased** across the first two years of the pandemic.[266] Moreover, the authors recommended that public health interventions prioritize children and adolescents with complex medical problems and neurodisability, who had the highest risk regardless of SARS-CoV-2 variant.[267]

In fact, the CDC's MMWR data reflected findings similar to the United Kingdom study. The CDC's April 2022 MMWR analyzed its COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) data, which included population-based surveillance for 1,475 laboratory-confirmed COVID-19–associated hospitalizations among children aged 5-11 years in 99 counties across 14 U.S. states between March 1, 2020, and February 28, 2022.[268]

The data showed that the total number of hospitalizations decreased with each subsequent SARS-CoV-2 variant (pre-Delta, Delta, Omicron), with Omicron-related hospitalizations accounting for around 27 percent of all COVID-19 associated hospitalizations in the sample (compared to 33 percent during Delta and 40 percent during pre-Delta).[269] Nearly 70 percent of hospitalizations were in children with underlying medical conditions and "[c]hildren with diabetes and obesity were more likely to experience severe COVID-19."[270] Moreover, less than 20 percent of all hospitalizations resulted in admission to an intensive care unit (ICU).[271] Even at the height of the Delta and Omicron peaks, weekly hospitalization rates of children aged 5-11 years was 1.2 per 100,000 children (Delta) and 2.8 per 100,000 children (Omicron).[272]

B. CDC Admits to Overcounting COVID-19 Deaths

In March of 2022, the CDC admitted to overcounting COVID-19 deaths. This overcounting was associated with a faulty algorithm in the CDC COVID Data Tracker's mortality data.[273] The

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[266] Joseph L. Ward et al., *Pediatric Hospitalizations and ICU Admissions Due to COVID-19 and Pediatric Inflammatory Multisystem Syndrome Temporally Associated With SARS-CoV-2 in England*, JAMA Pediatrics (July 31, 2023), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2807910.
[267] *Id.*
[268] Dallas S. Shi et al., *Hospitalizations of Children Aged 5-11 Years with Laboratory-Confirmed COVID-19—COVID-NET, 14 States, March 2020-February 2022*, 71 Morbidity & Mortality Wkly. 574-581 (Apr. 22, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7116e1 htm.
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] *Id.*
[273] *CDC Reports Fewer COVID-19 Pediatric Deaths After Data Correction*, Reuters (Mar. 18, 2022), https://www reuters.com/business/healthcare-pharmaceuticals/cdc-reports-fewer-covid-19-pediatric-deaths-after-data-correction-2022-03-18/.

overcounting applied to death tallies in **all age-groups**, including children. After the CDC recalculated, the number of pediatric deaths decreased by 24 percent.[274] At the same time, data from the American Academy of Pediatrics showed **pediatric deaths accounted for less than 0.26 percent of all COVID-19 deaths**.[275] An independent analysis found 25 instances where the CDC reported statistical or numerical errors in relation to its COVID-19 data.[276] 80 percent of these errors exaggerated the severity of the COVID-19 situation.[277]

The fact that HHS's COVID-19 pandemic policies, guidance, and recommendations, including Campaign messaging, were grounded in incorrect data generated by a faulty algorithm that had inflated the number of COVID-19 deaths shattered HHS's remaining credibility. The CDC's admission to overcounting deaths undermined the Campaign's promotional materials. The Campaign's messaging pressured parents to believe their children were facing life-or-death scenarios. By using artificially inflated child mortality rates, the Campaign greatly overstated the threat facing children and struck unnecessary fear into households everywhere.

Parents felt betrayed, and those who resisted or tuned out the warnings felt vindicated.

C. The Biden Administration Aggressively Pushed Boosters for Children and Adolescents

On January 3, 2022, the FDA amended its EUA for Pfizer's COVID-19 vaccine to expand single booster doses to adolescents 12-15 years of age.[278] On January 5, 2022, ACIP supported the FDA's recommendation. The same day, the CDC endorsed ACIP's recommendation and recommended those in the 12-17 year age group receive a booster dose 5 months after their initial Pfizer vaccination series.[279] Disturbingly, when CDC's ACIP met to consider expanding eligibility of booster doses to those 12-15 years old, it had no concrete evidence that booster doses would provide any protection from the virus for those in that age bracket. Slides from ACIP's January 5 meeting read, "**Impact of booster dose on neutralizing antibody or VE [vaccine effectiveness]**

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[274] *Id.*
[275] *Id.*
[276] Kelley Krohnert et al., *Statistical and Numerical Errors Made by the US Centers for Disease Control and Prevention During the COVID-19 Pandemic*, Social Sci. Res. Network (SSRN) (Mar. 23, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381627.
[277] *Id.*
[278] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine (Jan. 3, 2022), https://web.archive.org/web/20220103144625/https://www fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine.
[279] Press Release, Ctrs. for Disease Control & Prevention, CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds (Jan. 5, 2022), https://www.cdc.gov/media/releases/2022/s0105-Booster-Shot.html.

in adolescents 12–15 years of age is unknown, but likely to provide additional protection (emphasis added)."[280]

On May 17, 2022, the FDA expanded eligibility for Pfizer-BioNTech COVID-19 vaccine booster dose to children 5-11 years old.[281] Two days later on May 19, CDC's ACIP voted (11-1, 1 abstained) in favor of recommending a single Pfizer-BioNTech COVID-19 vaccine booster dose for those in the 5–11-year age group at least 5 months after completion of a Pfizer-BioNTech COVID-19 vaccine primary series.[282]

i. CDC Goes it Alone, Recommends COVID-19 Shots for Children Six Months to Four Years, Followed by Universal Booster Campaign

On June 18, 2022, the CDC recommended COVID-19 vaccines for children as young as 6 months and up to five years.[283] In making the recommendation, CDC's ACIP determined that both Moderna and Pfizer COVID-19 vaccines "met the criteria for immunobridging, which is the comparison of neutralizing antibody levels postvaccination in young children with those in young adults in whom efficacy had been demonstrated."[284] The CDC based its recommendation for vaccinating very young children based almost exclusively on evidence of an immune response, as opposed to evidence of vaccine effectiveness in preventing illness.

CDC's ACIP found the measure of immune response to two doses of the Moderna vaccine in children aged 6–23 months and 2–5 years without evidence of previous SARS-CoV-2 infection "was at least as high as the response observed in young adults aged 18–25 years" who had received two doses of the Moderna vaccine.[285] Similarly, in the analysis for the Pfizer vaccine, ACIP found

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[280] Sara Oliver, *Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech Vaccine Booster Doses in 12–15 Year Olds,* Ctr. for Disease Control & Prevention (Jan. 5, 2022), https://web.archive.org/web/20240515131228/https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06_COVID_Oliver_2022-01-05.pdf.

[281] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years (May 17, 2022), https://web.archive.org/web/20220601010756/https://www fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose; *COVID-19 Vaccines*, *Coronavirus (COVID-19)*, U.S. Dep't of Health & Hum. Servs., https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html (last accessed Mar. 13, 2024).

[282] *ACIP Update to the Evidence to Recommendations for a Pfizer-BioNTech COVID-19 Booster in Children Ages 5-11 Years,* Ctr. For Disease Control & Prevention (Nat'l Ctr. for Immunization & Respiratory Diseases), https://web.archive.org/web/20240616214628/https://www.cdc.gov/vaccines/acip/recs/grade/pfizer-biontech-covid19-booster-children-etr.html (last updated May 31, 2022).

[283] Jacqueline Howard, *CDC Recommends Covid-19 Vaccines for Children as Young as 6 Months, Clearing the Way for Vaccinations to Begin Soon*, CNN (June 18, 2022), https://www.cnn.com/2022/06/18/health/cdc-covid-vaccine-children-under-5/index.html.

[284] Katherine E. Fleming-Dutra et al, *Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022*, CDC (July 1, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7126e2 htm.

[285] *Id.*

"the measure of immune response to 3 doses (3 µg each) of the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in persons aged 16–25 years who had received 2 doses (30 µg each) of the Pfizer-BioNTech COVID-19 vaccine."[286]

However, vaccine efficacy fourteen days after the second dose of the Moderna vaccine was only 37.8 percent in preventing **symptomatic**, laboratory-confirmed COVID-19 in children aged 6 months—5 years with or without evidence of previous COVID infection, based on a sample size of 181 vaccine recipients and 97 placebo recipients (n=278 recipients), none of whom were hospitalized.[287] At the same time, vaccine efficacy against **asymptomatic**, laboratory-confirmed COVID-19 infection in children aged 6 months—5 years with or without evidence of previous COVID infection was a mere 16 percent, based on a sample size of 111 vaccine recipients and 44 placebo recipients (n=155).[288]

Vaccine efficacy more than seven days after the third dose of the Pfizer vaccine was 80 percent in preventing **symptomatic**, laboratory-confirmed COVID-19 in children aged 6 months—4 years with and without evidence of previous COVID infection.[289] However, this number was based on a sample size of 10 recipients, including three vaccine recipients and seven placebo recipients. None of the study participants were hospitalized.[290] ACIP's recommendation also included the following comments:

> From the GRADE[291] evidence assessment, the level of certainty for the benefits of Pfizer-BioNTech COVID-19 vaccination among children aged 6 months–4 years was type 4 (very low certainty) for the prevention of symptomatic laboratory-confirmed COVID-19 assessed using direct efficacy because of serious concern about the short duration of follow-up (median = 35 and 40 days for children aged 6–23 months and 2–4 years, respectively) and very serious concerns about imprecision because of case accrual and study size. For the prevention of symptomatic, laboratory-confirmed COVID-19 assessed using immunobridging, the evidence was type 2 (moderate certainty) because of serious concerns for indirectness,

[286] *Id.*
[287] *Id.*
[288] *Id.*
[289] *Id.*
[290] *Id.*
[291] CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE). *About Grade*, CDC: Advisory Committee on Immunization Practices, https://web.archive.org/web/20240730070356/https://www.cdc.gov/vaccines/acip/recs/grade/about-grade html (last accessed May 22, 2024).

> because immunogenicity is a surrogate measure of efficacy. Regarding potential harms after vaccination, the evidence was type 4 (very low certainty) for serious adverse events because of very serious concerns for indirectness because of the short duration of follow-up of 1 month after dose 3 and because only 31% of trial participants received dose 3, limiting the ability to detect serious adverse events that might occur at a higher rate after dose 3, and serious concern of imprecision because of the study size.[292]

Notably, ACIP's recommendation did not include statistics on the efficacy of the Pfizer vaccine against **asymptomatic**, laboratory-confirmed COVID-19 infection in children aged 6 months—4 years with or without evidence of previous COVID infection.

ACIP justified its recommendation for the use of Moderna and Pfizer COVID-19 vaccines in children ages 6 months to 5 years with the vague conclusion that it was of "public health importance."[293] In presenting its evidence, ACIP outlined COVID-19 infection rates among infants and children in the U.S., as well as increased hospitalization rates during the Omicron surge.[294] However, ACIP acknowledged children under 18 years of age infected with COVID "are less likely to develop severe illness compared with adults."[295] Moreover, ACIP's evidence showed that as of May 11, 2022, a month prior to expanding COVID-19 vaccines for infants and young children, COVID-19 "related" deaths among children 6 months to 4 years accounted for 1.7 percent of all deaths among children in this age group.[296]

Nevertheless, ACIP made the recommendation to vaccinate because "children are still at risk of developing severe illness and complications from COVID-19 and contribute to transmission in households and communities."[297] This was another example of the Biden-Harris administration basing a recommendation, at least partially, on the belief that COVID-19 vaccines were effective against transmission, despite that claim not being supported by the manufacturers or the FDA. The CDC maintained its posture of broadly recommending COVID-19 vaccines for children despite

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[292] Katherine E. Fleming-Dutra et al., *Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022*, CDC (July 1, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7126e2 htm.
[293] *ACIP Evidence to Recommendations for Use of Moderna COVID-19 Vaccine in Children Ages 6 Months – 5 Years and Pfizer-BioNTech COVID-19 Vaccine in Children Ages 6 Months – 4 Years under an Emergency Use Authorization*, CDC, https://web.archive.org/web/20240808100414/https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-pfizer-children-vaccine-etr.html (June 27, 2022).
[294] *Id.*
[295] *Id.*
[296] *Id.*
[297] *Id.*

acknowledging the overcounting of COVID-19 deaths among all age groups, including children just a few months earlier.[298]

On cue with the CDC's recommendation, the Campaign released ads targeting parents of newborns as early as June 23, 2022:

> June 23, 2022: Promise – COVID-19 Vaccines[299]
> Ad opens up with scenes of 6-month-old babies crawling and informs audience that all kids 6 months and up can get the vaccine. "Parents have more than one way to keep them safe."
>
> Promise: COVID-19 Vaccines (Video)[300]
> "Nothing matters more than keeping them safe. If your child is 6 months old and older, you can now help protect them from severe COVID illness by getting them a COVID vaccine."
>
> August 24, 2022: Ask a Doctor: Will a vaccine help protect my child from COVID? (Video)[301]
> "Make sure your child is up to date on vaccines and boosters helps protect them from COVID symptoms that can last for weeks and even months after the infection. This is sometimes called "long COVID". After getting covid, children and teens can experience a wide range of health problems that may affect their quality of life such as extreme tiredness or difficulty thinking and concentrating."

At times, the messages painted anyone who disagreed with the CDC's recommendations as anti-science. The message was simple: if you get vaccinated, you are **for** science, if you do not, you are **anti-science**.

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[298] *See supra* CDC Admits to Overcounting COVID-19 Deaths, pgs. 63-64.
[299] U.S. Dep't of Health & Hum. Servs., *Promise: COVID-19 Vaccines*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 23, 2022), https://www.youtube.com/watch?v=VOWOB6mcOfU&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=4 (content removed by HHS. No longer publicly available as of June 2024).
[300] U.S. Dep't of Health & Hum. Servs., *Promise: COVID-19 Vaccines*, *Parents and COVID-19 Vaccines Collection*, YouTube (June 23, 2022), https://www.youtube.com/watch?v=z8H7FHMP3Kk (content removed by HHS. No longer publicly available as of June 2024).
[301] U.S. Dep't of Health & Hum. Servs., *Ask a Doctor: Will a vaccine help protect my child from COVID?*, *Parents and COVID-19 Vaccines Collection*, YouTube (Aug. 24, 2022), https://www.youtube.com/watch?v=Qh1I0QUkTVk (content removed by HHS. No longer publicly available as of June 2024).

My Family's Vaccination Story | Blog post (9.10.22)[302]
Ultimately, we knew there was no way of knowing how Braeden would react to the COVID vaccine. But we took great comfort in knowing clinical trials have shown vaccines help prevent severe illness and death from COVID.

We asked Braeden how he felt about getting vaccinated, and he told us he was counting down the days until he could get his shot. Chris and I felt good about our decision to get Braeden vaccinated, and we received our son's enthusiastic consent. On the big day, we went as a family. Braeden proudly stated his name when the kind nurse asked him, and he rolled up his sleeve. As he received his vaccination, Chris and I teared up. For the first time in what felt like forever, we breathed a little easier. And when we asked Braeden how he felt, he said, "I feel safe!"

Ask a Doctor: My child doesn't have any health problems. Why do they need a COVID vaccine? (Video) (9.29.22)[303]
"So the vaccine is an added layer of protection of keeping your child out of the hospital or becoming severely ill. **It doesn't really matter if your child's completely healthy, because some children will have the sniffles, maybe signs like the flu; fever, runny nose, or body aches. But others will end up in the hospital and end up there for a long time.** So we really want to keep your child safe (emphasis added)."

Sept 29, 2022: Ask a Doctor: Do kids get long-term side effects from COVID vaccines? (Video)[304]

We're not anticipating any long-term side effects. What we do know is that there are some short-term side effects that can lead to the child

[302] Laura Proud, My Family's Vaccination Story, Plus Mommy, https://plusmommy.com/vaccination-story/ (last visited July 2024).
[303] U.S. Dep't of Health & Hum. Servs., *Ask a Doctor: My child doesn't have any health problems. Why do they need a COVID vaccine?*, *Parents and COVID-19 Vaccines Collection*, YouTube (Sept. 29, 2022), https://www.youtube.com/watch?v=z-Ta41CIxvE (content removed by HHS. No longer publicly available as of June 2024).
[304] U.S. Dep't of Health & Hum. Servs., *Ask a Doctor: Do kids get long-term side effects from COVID vaccines?*, *Parents and COVID-19 Vaccines Collection*, YouTube (Sept. 29, 2022), https://www.youtube.com/watch?v=7ubvS9E95WI (content removed by HHS. No longer publicly available as of June 2024).

having some soreness in the arm, maybe fever, having some sleepiness, feeling tired, which are all very common…."

Ask Dr. Thomas: How can I prepare my child for their COVID-19 vaccine appointment? (10.19.22)[305]
"You can also explain that vaccines are a way to stay healthy and help protect others; **it's powerful for kids to know they're making a difference** (emphasis added)."

On August 31, 2022, the FDA authorized Moderna and Pfizer COVID-19 vaccines for use as a booster dose in children 12 years and older.[306] On September 1, 2022, ACIP voted (13-1) in favor of recommending a single dose of the bivalent Pfizer COVID-19 vaccine as a booster dose in children 12 years and older under FDA's EUA.[307] At the time, ACIP only recommended the Moderna bivalent booster vaccine for adults over 18 years.

By October 12, 2022, the FDA had authorized bivalent booster doses of the Moderna and Pfizer COVID vaccines in younger age groups.[308] The bivalent Pfizer and Moderna boosters were authorized for administration at least two months following completion of a primary series or booster vaccination in children as young as five and six years of age, respectively.[309] The same day, the CDC expanded its recommendation to allow administration of a single dose of the bivalent Pfizer booster in children five years and older.[310] In December, the FDA authorized use of the bivalent Moderna and Pfizer vaccines in children as young as six months.[311] Between December 2022–April 2023, the CDC "made recommendations for a single bivalent vaccine dose for most

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[305] U.S. Dep't of Health & Hum. Servs., *Ask Dr. Thomas: How can I prepare my child for their COVID-19 vaccine appointment?*, *Parents and COVID-19 Vaccines Collection*, YouTube (Oct. 19, 2022), https://www.youtube.com/watch?v=NEgVs3vzO3M (content removed by HHS. No longer publicly available as of June 2024).
[306] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as Booster Dose (Aug. 31, 2022), https://web.archive.org/web/20240116174331/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.
[307] Hannah G. Rosenblum et al., *Interim Recommendations from the Advisory Committee on Immunization Practices for the Use of Bivalent Booster Doses of COVID-19 Vaccines — United States, October 2022*, CDC (Nov. 11, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7145a2.htm.
[308] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups (Oct. 12, 2022), https://web.archive.org/web/20240112132023/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines.
[309] *Id.*
[310] Danielle L. Moulia et al., *Interim Recommendations for Use of Bivalent mRNA COVID-19 Vaccines for Persons Aged ≥6 Months — United States, April 2023*, CDC, (Nov. 11, 2023), https://www.cdc.gov/mmwr/volumes/71/wr/mm7145a2.htm.
[311] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Updated (Bivalent) COVID-19 Vaccines for Children Down to 6 Months of Age (Dec. 8, 2022), https://web.archive.org/web/20230327100821/https://www fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-updated-bivalent-covid-19-vaccines-children-down-6-months.

persons aged ≥6 years, bivalent vaccines for children aged 6 months–5 years, and optional additional bivalent booster doses for moderately or severely immunocompromised persons aged ≥6 months and adults aged ≥65 years."[312]

Despite CDC recommendations, an analysis of child and adolescent COVID-19 vaccination coverage, published in the *Annals of Medicine* in July of 2023, found only 13.2 percent of children under five years and 43.9 percent of children 5–11 years had completed a primary vaccination series.[313] Additionally, "[b]ooster vaccination among those who completed the primary series was 39.1% among children 5–11 years and 55.3% among adolescents 12–17 years."[314] The study found parental reluctance to vaccinate was highest for children younger than five years of age (46.8 percent).[315] The "[m]ain reasons for non-vaccination among reluctant parents were concerns about side effects (53.3%), lack of trust in COVID-19 vaccines (48.7%), the belief that children do not need a COVID-19 vaccine (38.8%), lack of trust in the government (35.6%), and that children in the household were not members of a high-risk group (32.8%)."[316]

Today, CDC continues to recommend booster shots for all children ages six months and older, making the U.S. an outlier amongst its international peers. Despite the recommendation, only about five percent of children under age 12 are up to date on their boosters.[317] In June of 2024, the *New York Times* called CDC's continued recommendation of boosters for young children yet another practice that "makes for a case study of the shortcomings in U.S. Covid policy," joining the laundry list of extended school closures and mask mandates[318]

In stark contrast, a large part of the world, including countries such as the United Kingdom, France, Japan, and Australia, have reached a different conclusion—that most children do not need to receive COVID-19 booster shots.[319] In India, healthy children no longer receive a COVID-19 primary vaccine series.[320] German public health experts only recommend vaccines for teenagers and children with medical conditions.[321] These countries have revised COVID-19 primary vaccine and booster guidance because they have found the benefits conferred by COVID-19 vaccines to

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[312] Danielle L. Moulia et al., *Interim Recommendations for Use of Bivalent mRNA COVID-19 Vaccines for Persons Aged ≥6 Months — United States, April 2023*, CDC (June 16, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7224a3.htm.
[313] Kimberly H. Nguyen et al, *Disparities in child and adolescent COVID-19 vaccination coverage and parental intent toward vaccinations for their children and adolescents*, 55 Annals of Medicine 1, 6 (July 14, 2023), https://www.tandfonline.com/doi/full/10.1080/07853890.2023.2232818.
[314] *Id.*
[315] *Id.*
[316] *Id.*
[317] David Leonhardt, *Covid Shots for Children*, N.Y. Times (Feb. 13, 2024), https://www nytimes.com/2024/02/13/briefing/covid-boosters-children-cdc html.
[318] *Id.*
[319] *Id.*
[320] *Id.*
[321] *Id.*

children are "modest."[322] First, children are "extremely unlikely to become seriously ill from Covid and are less likely to transmit the virus" than adults.[323] Second, the costs of vaccination, including "the financial price of mass vaccination, the possibility that a shot's side effects will make a child sick enough to miss school, the tiny chance of more serious side effects and the inherent uncertainty about long-term effects" all far outweigh any demonstrated benefits.[324]

In December of 2023, a previous interview with former NIH Director Francis Collins surfaced where Collins "admitted to having a 'narrow,' 'really unfortunate' mindset during the Covid-19 pandemic that prevented himself and other public health officials from considering the potential collateral damage of their decisions."[325] The CDC's ongoing booster recommendation for children as young as six months of age suggests the agency has not deviated, nor learned any lessons, from this narrow-mindedness. Public health experts continue to warn that the CDC's recommendations have a lasting impact on its credibility. The CDC's insistence on a vaccine with marginal benefit has also unfortunately led the public to question other agency guidance, such as the efficacy and need for routine childhood vaccinations against measles and diphtheria. Data has shown that the percentage of kindergarteners vaccinated with all state-required vaccines, including MMR, DTaP, polio, and varicella, is dropping relative to pre-pandemic levels.[326] At the same time, the numbers of kindergarteners requesting an exemption from one or more required vaccinations increased from pre-pandemic levels to its highest level to date.[327]

VII. Recommendations

In light of the aforementioned findings, the Committee makes the following recommendations:

- **Congress should consider formally authorizing the CDC and clearly define the agency's core mission.** The CDC, unlike other major agencies, has never received full Congressional authorization. There is no single enabling statute that defines the agency's overall mission and structure.[328] The lack of authorization has blurred the lines on the agency's responsibilities to lead on issues related to communicable disease, resulted in rampant mission creep, and has led many to question whether the CDC is able to execute on its

[322] *Id.*
[323] *Id.*
[324] *Id.*
[325] Isaac Schorr, *Former National Institutes of Health Director Admits to 'Narrow,' 'Really Unfortunate' Pandemic Mindset: 'We Weren't Thinking' About Collateral Damage*, MediaIte (Dec. 28, 2023), https://www mediaite.com/news/former-national-institutes-of-health-director-admits-to-narrow-really-unfortunate-pandemic-mindset-we-werent-thinking-about-collateral-damage/#article-nav.
[326] Elizabeth Williams & Robin Rudowitz, *Headed Back to School in 2024: An Update on Children's Routine Vaccination Trends*, KFF (July 18, 2024), https://www.kff.org/coronavirus-covid-19/issue-brief/headed-back-to-school-in-2024-an-update-on-childrens-routine-vaccination-trends/.
[327] *Id.*
[328] Kavya Sekar, Cong. Rsch. Serv., IF12241, Ctrs. for Disease Control and Prevention (2023), https://crsreports.congress.gov/product/pdf/IF/IF12241.

intended and primary mission of detecting and combatting public health threats, as evidenced by the CDC's botched handling of the COVID-19 response. Congressional authorization should outline the agency's core mission, delineate roles and responsibilities, and reevaluate its involvement in broad prevention initiatives outside the scope of the agency's core mission, such as climate initiatives, as well as duplicative programs addressed by other agencies both inside and outside HHS. Congress should also consider whether to separate the CDC's public health functions from its chronic disease research activities.

- **HHS and its agencies should abide by the FDA's product labeling guidelines. HHS and its agencies should be barred from promoting information regarding an FDA-regulated product that does not reflect the FDA-approved label.** FDA product labels are authorized or approved only after extensive review and play a major role in the presentation of safety and effectiveness information.[329] Public health messaging by all HHS departments must abide by the product labeling guidelines and be barred from promoting messages that go beyond, or otherwise conflict with, the approved or authorized label for a vaccine, drug, or related product. In December of 2020, when the Pfizer-BioNTech COVID-19 vaccine received EUA to be distributed in the U.S., the FDA press release explicitly stated "[a]t this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person."[330] Despite this disclosure, high ranking federal officials, including President Biden, **knowingly** made unsubstantiated claims about the effectiveness of the COVID-19 vaccines. These declarations continued even after breakthrough infections began to occur. The "pandemic of the vaccinated" motto was divisive and extremely damaging, as it led the public to believe unvaccinated individuals were the cause of continued viral transmission, when that simply was not true. A study published in October of 2021 by the University of California, Davis, found no significant difference in viral loads between vaccinated and unvaccinated individuals, which signaled COVID-19 vaccines did not prevent infection nor transmission.[331] Moreover, the CDC enforced life-altering mandates on the public based on unsubstantiated claims. CDC and other federal officials must be held to the same standards as companies when it comes to promoting message about FDA authorized or approved products.

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[329] Hassan Z. Sheikh, Cong. Rsch. Serv., R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness (May 8, 2018), https://crsreports.congress.gov/product/pdf/R/R41983.
[330] Press Release, Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.
[331] Charlotte B. Acharya et al., *Viral Load Among Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Persons Infected With the SARS-CoV-2 Delta Variant*, *Open Forum Infectious Diseases,* (Mar. 17, 2022) https://doi.org/10.1093/ofid/ofac135.

- **Congress should consider clarifying responsibility for evaluating the safety of vaccines and streamline existing reporting systems for capturing vaccine injuries and adverse reactions.** There continues to be concerns over the safety of COVID-19 vaccines, including the risk of myocarditis and blood clots. The CDC's Vaccine Adverse Event Reporting System (VAERS) database is a passive surveillance system that does not establish a causal relationship between vaccine administration and the adverse event. VAERS reporting of COVID-19 vaccine injuries proved highly controversial. The FDA also monitors the safety of approved products through the FDA Adverse Event Reporting System (FAERS), MedWatch, and the Sentinel Initiative. When compared to VAERS, the FDA's adverse events reporting systems appears to offer a more robust method of capturing adverse events that relies on both active and passive surveillance. Streamlining adverse events surveillance would avoid duplication and provide clear, reliable guidance on the emergence of vaccine and other related adverse events.

- **HHS and its agencies should embrace a culture of transparency and accountability.** There has been a growing body of evidence on the societal damage resulting from CDC-imposed mask and travel mandates, social distancing requirements, school closure guidance, and vaccine recommendations. In addition, the data supporting the benefits of such policies has been lacking throughout the pandemic and afterwards. Through the course of the pandemic and in the aftermath, one thing has become clear: the CDC did not operate in a culture of transparency. This must change.

  The agency must embrace transparency and be willing to admit what it does and **does not know**. The CDC must communicate clearly and honestly when its recommendations have been proven and when they are based on untested hypotheses. Instead of promulgating policy to inform the science, the agency must allow the science to promulgate the policy. To this end, the agency should establish procedures for conferring with public health bodies from local, state, and foreign governments and be willing to modify its policies based on emerging science and best practices recommended by outside experts at home and abroad.

  As outlined in H.R.4529, the *Public Health Guidance Transparency and Accountability Act of 2023*, the CDC Director should be required to develop, establish, and maintain good guidance practices. These guidance documents must include public participation and be non-binding on the public and government. The agency should routinely update these best practices.[332]

- **The CDC and federal public health officials should not attempt to silence dissenting scientific opinions.** Congress should safeguard medical and scientific debate from attempted

[332] *Crisis and Emergency Risk Communication Manual*, CDC: Emergency Preparedness and Response, https://emergency.cdc.gov/cerc/manual/index.asp (last updated 2019).

government suppression, particularly during public health emergencies, and consider appropriate legislation consistent with the First Amendment.

- **HHS and its agencies should overhaul their website archival process to mimic that of prior White House administrations.** Throughout the writing of this report, the CDC continued to edit and erase website content unannounced. The agency's lack of notice to changes in its record keeping and poor archival process made it nearly impossible to track down former agency actions. While parts of CDC's former COVID-19 health guidance have been preserved on its COVID-19 Museum Timeline—albeit the more favorable parts of such guidance—the CDC has also entirely erased and replaced unscientific guidance, blatant errors, and unfavorable press releases. During the writing of this report, HHS abruptly restricted public access to view its Campaign content that was previously widely available on YouTube. These videos are no longer accessible to the public. Such editing and erasing of guidance and web content on its government-controlled website, and making taxpayer funded Campaign videos inaccessible is unacceptable, particularly considering the historic and life-altering nature of the COVID-19 pandemic. HHS must ensure proper record-keeping of its website content that comports with the same archival process as prior White House administrations.

VIII. Appendix

This Appendix describes how the HHS and the NIH disbursed one billion dollars in taxpayer funding, the process behind FMG's design of the Campaign, and the data collection FMG undertook as it sought to measure the public's attitudes towards various pandemic related occurrences.

Launching the Campaign

The NIH's Office of Logistics and Acquisition Operations (OLAO) administers award task orders through the "Public Information and Communication Services II" (PICS II) contract vehicle to provide communications goods and services to the NIH, as well as other HHS agencies and offices.[333] OLAO initially awarded the contract vehicle in 2018 with a maximum total award value of $500 million but, due to the COVID-19 pandemic, the award ceiling was doubled to $1 billion in 2021.[334] The PICS II contract vehicle expired in December 2023, but in June 2022, OLAO began the process of soliciting sources for the PICS III contract vehicle.[335]

In April 2023, the Committee initiated an investigation into the PICS II contract to account for the amount and purpose of the public relations and communications task orders, including those provided for the COVID-19 public education campaign.[336] First, the Committee sent letters to the 10 vendors that were selected under the PICS II contract.[337] In the letters, the Committee requested documentation and details about the task orders awarded to each vendor, including a description of services provided, the funded amounts, sponsoring offices, and periods of performance.[338] The Committee also requested copies of deliverables that were produced under each task order, such as public relations materials and media advertisements.

After reviewing the materials provided by the 10 vendors, the Committee requested additional documentation from the Fors Marsh Group (FMG) on the three task orders that funded the Campaign given the significant amount of money obligated in the task orders. The Committee

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[333] A task order is an order for goods and services placed against an established contract. *About Us: PICS II*, NIH Off. of Logistics & Acquisition Operations, https://pics.olao.od nih.gov/about.html (last accessed July 30, 2024).
[334] Public Information & Communication Services Contract II (PICS II) Pre Sol/Special Notice, Notice ID: NIHODSN61821, SAM.gov, (June 21, 2021), https://sam.gov/opp/127bc632b6234b8ca7f8c8d3d834dab5/view#general (citing a need for increased funding due to an "unprecedented need for [marketing and advertising] services").
[335] NIH Public Information and Communication Services Contract III (PICS III), Notice ID: 2022-0001, SAM.gov, (June 16, 2022), https://sam.gov/opp/efb0373a8ba64a4ca848b140f55d01a0/view.
[336] Press Release, The Hon. Cathy McMorris Rodgers et al., H. Comm. on Energy & Com., E&C Republicans Launch Probe in NIH's Billion-Dollar Public Relations Spending Spree (Apr. 25, 2023), https://energycommerce house.gov/posts/e-and-c-republicans-launch-probe-in-nih-s-billion-dollar-public-relations-spending-spree.
[337] *Id.*
[338] *Id.*

requested and reviewed material FMG developed during the Campaign, including monthly progress reports and briefs submitted by FMG to the Assistant Secretary for Public Affairs (ASPA), findings from surveys and other data collection tools, advertisements and promotional media, and information on partners who worked with FMG to disseminate information.

ASPA Provided Fors Marsh Group with $911 Million for the COVID-19 Public Education Campaign

Based on the Committee's review of each vendor's task orders, the Committee found that OLAO awarded at least 70 task orders through the PICS II contract totaling $1 billion. However, a significant majority of that funding ($911 million) was awarded to FMG for the ASPA COVID-19 Public Education Campaign (Table 1).

Table 1: ASPA Task Orders Provided to Fors Marsh Group

Task Order Request for Proposal Number	Amount	Period of Performance Start Date	Period of Performance End Date
#2041	$300,023,797.18	08/31/2020	11/30/2021
#2056	$188,303,478.28	7/30/2021	4/30/2022
#2070	$422,847,009.85	1/7/2022	7/6/2023
Total	**$911,174,285.31**		

Source: Fors Marsh Group, FMG000001(on file with Committee).

Excluding the three COVID-19 task orders, PICS II task orders were typically valued under $10 million, with many others valued under $1 million.[339] These task orders were typically used to supply services such as website design and support services, technical support for workshops and conferences, and public health awareness and outreach campaigns.

For example, IQ Solutions was awarded roughly $2.2 million to support the National Cancer Institute's Exhibit and Conference Management program, which helps present the Institute's mission and programs at national and international conferences.[340] Further, Hendall, Inc., received a task order worth $750,000 to provide the National Institute of Dental and Craniofacial Research with copy editing, publishing assistance, and communications support for the 2020 Surgeon General's Report on Oral Health.[341]

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[339] Review of production documents (on file with Committee).
[340] Review of production documents (on file with Committee).
[341] Francis Collins, *Oral Health in America: Advances and Challenge*, US Department of Health and Human Services, National Institutes of Health, National Institute of Dental and Craniofacial Research (Dec. 2021), https://www.nidcr.nih.gov/sites/default/files/2021-12/Oral-Health-in-America-Advances-and-Challenges.pdf.

FMG received the three ASPA COVID-19 Public Education Campaign task orders, and the company also received 13 other task orders under the PICS II contract vehicle with award ceilings as high as $3.8 million and as low as $81,600. These included task orders to assist in usability testing the FDA's website, supporting the NIH Office of Management public website, developing recruitment and participation strategies for Alzheimer's studies, and providing communications and support services to the National Institute of Neurological Disorders and Strokes.

The "We Can Do This" Campaign Used Various Outreach and Engagement Strategies to Encourage Uptake of COVID-19 Vaccines and Boosters

In August 2020, FMG was awarded the first of the three ASPA task orders, which the company used to fund the Campaign. FMG designed the Campaign to persuade Americans to get COVID-19 vaccines and boosters, as well as to encourage the public to adopt behaviors, such as masking and social distancing, that CDC and the Biden-Harris administration hoped would curb viral spread. Based on reports shared with the Committee, FMG spent on average over $20 million per month for the design and execution of the Campaign.[342] As a self-described full-service behavior change research and strategy firm, FMG had experience reaching wide audiences, especially hard-to-count audiences, from its work on the 2020 Census campaign. In its proposal for the task order, the company asserted that it could benefit the ASPA by using a strategic mix of paid and earned media with exclusive radio partnerships, research-based messaging, and reinforced messaging from trusted influencers, celebrities, and sports figures.[343]

FMG's Campaign strategies were grounded in several theories of behavior change and communication, namely the theory of planned behavior, the health belief model, and the transtheoretical (stages of change) model, "with the expectation that exposure to Campaign messages prompts change in cognitions antecedent to Campaign-targeted behavior."[344] The health belief model submits that "a person's belief in a personal threat of an illness or disease together with a person's belief in the effectiveness of the recommended health behavior or action will predict the likelihood the person will adopt the behavior."[345] The transtheoretical (stages of change) model, theorizes that individuals move through six stages of change across a continuum

[342] Fors Marsh Group, VacciNation Forward, FMG000528 (July 16, 2021) (on file with Committee).
[343] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000498 (Aug. 14, 2020) (on file with Committee).
[344] Elissa C. Kranzler et al., *Recalled Exposure to COVID-19 Public Education Campaign Advertisements Predicts COVID-19 Vaccine Confidence*, J. Health Comm. 28:3, 144-155 (2023), DOI: 10.1080/10810730.2023.2181891.
[345] The Health Belief Model, Boston University, Nov. 3, 2022, https://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories2.html.

from contemplation to action.[346] The theory of planned behavior states that behavioral achievement depends on both motivation (intention) and ability (behavioral control).[347]

Utilizing protocols and best practices from prior FDA and CDC-led public health campaigns for tobacco prevention and control, FMG and its partners created ads and designed outreach strategies that specifically targeted different demographic groups and population segments. [348] Through these strategies and aforementioned behavioral science principles, FMG sought to change public behavior around COVID-19 and "to effectively move the public toward action" (that is, getting vaccinated, and abiding by social distancing and masking requirements).[349] In its proposal for the task order, FMG outlined how it planned to apply the drivers of behavior from the model to the campaign messaging strategy.[350] In short, FMG planned to use CDC guidance, recommendations, and internal scientific research to convince the American people that COVID-19 posed a sufficient threat to them or their loved ones that they should follow the government's recommendations and mandates.

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[346] The Transtheoretical Model (Stages of Change), Boston University, Nov. 3, 2022, https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/behavioralchangetheories6 html.
[347] The Theory of Planned Behavior, Boston University, Nov. 3, 2022, https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/BehavioralChangeTheories3 html.
[348] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000505 (Aug. 14, 2020) (on file with Committee).
[349] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000499 (Aug. 14, 2020) (on file with Committee).
[350] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000499 - FMG000500 (Aug. 14, 2020) (on file with Committee).

COVID-19 Campaign Messaging Based on Transtheoretical (Stages of Change) Model

Drivers	Definition	Application
Perceived Risk	Beliefs about chances of infection happening	Define population(s) at risk; personalize the risk to make it more "real" citing population-based COVID-19 infections; heighten risk perception if too low
Perceived Severity	Beliefs about seriousness/ consequences of infection	Communicate the consequences of COVID-19 (health, emotional and economic loss) by literally showing people through real life testimonials
Perceived Benefits	Belief about effectiveness and value of taking action to reduce risk	Explicitly show what recovery looks like (return to work and financial wellness); illustrate the future state of communities after taking the desired actions, such as restored state of normalcy, tell success stories from other communities
Perceived Barriers	Beliefs about the tangible and emotional costs of taking action	Identify and reduce barriers through reassurance, incentives, and assistance, and correcting misinformation, for example related to the efficacy of mask wearing and social interaction. Break down the complex picture into digestible pieces.
Cues to Action	Strategies that activate "readiness to change"	Provide how-to information such as videos showing COVID-19 testing; promote progress; keep the issue and dialogue alive throughout the process.
Self-Efficacy	Confidence in one's ability to take action	Provide training, technical assistance, and support to help find and access the best resources, such as small business owners accessing and properly using PPE or requiring patrons to follow contact-less policies.
Social Norming	Belief that others are also taking action	Showcase examples of hope and success such as in communities where mask mandates have prevented outbreaks; connect local issues to national dialogue.

Source: Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000499 (Aug. 14, 2020) (on file with Committee).

Throughout the duration of the Campaign, messaging and ad content was monitored using opinion surveys and other data collection tools, such as focus groups and representative surveys, to collect information on Americans' attitudes towards COVID-19 vaccines. FMG used behavioral science principles to create ads and outreach strategies that specifically targeted different demographic groups and population segments.

FMG deployed several data and information collection tools targeting different population groups, which served to inform Campaign strategies. The COVID-19 Attitudes and Beliefs Survey (CABS) was "a nationally representative, probability-sampled longitudinal survey of American adults administered every four months starting in January 2021."[351] This "35-minute, web-based survey measure[d] COVID-19 vaccination; attitudes and beliefs relevant to COVID-19 and preventive behaviors; recalled Campaign exposure; socio-demographic characteristics; and other items."[352]

The Current Events Tracker (CET) was a weekly probability-based survey of 1,000 representative U.S. adults that sought to understand changing vaccine attitudes, address emergent issues, and stay informed on attitudes in the general and key subpopulations. In addition, FMG engaged regular online panels (termed "Qualitative Insights Panels") consisting of key vaccine

[351] Elissa C. Kranzler et al., *Recalled Exposure to COVID-19 Public Education Campaign Advertisements Predicts COVID-19 Vaccine Confidence*, 28 J. Health Comm., 144-55 (2023), https://doi.org/10.1080/10810730.2023.2181891.
[352] *Id.*

hesitant audiences (e.g., unvaccinated adults, parents of unvaccinated children, and booster-hesitant adults) on an ongoing basis "to collect in-depth insights on emergent topics, understand nuanced reactions to current events, and solicit timely feedback on creative" materials.[353]

FMG also used social listening tools and search trends, situation briefings, qualitative data, and evaluation surveys on an ongoing basis to help design the Campaign. For population-based segmentation, FMG used national geographic segmentation tools that clustered ZIP codes with similar demographics, media usage/behaviors, and psychographics for creative development and media-planning activities.[354] According to documentation obtained by the Committee, FMG's strategic and creative content were tailored to have maximum impact with a "high probability of success."[355] These "successes" were then published in multiple peer-reviewed journal articles as a means to normalize Campaign strategies, as well as to influence the scientific community.[356]

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[353] Fors Marsh Group, VacciNation Forward, FMG000520 (July 16, 2021) (on file with Committee); Fors Marsh Group, Advancing vaccINTENT, FMG000541 (Dec. 30, 2021) (on file with Committee).
[354] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000504 (Aug. 14, 2020) (on file with Committee).
[355] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000505 (Aug. 14, 2020) (on file with Committee).
[356] Benjamin Denison et al., *Association Between the "We Can Do This" Campaign and COVID-19 Booster Uptake, U.S., 2021–2022*, AJPM Focus (Jan. 4, 2024), https://doi.org/10.1016/j.focus.2024.100183; Joseph N. Luchman et al., *Association Between the United States Department of Health and Human Services' COVID-19 Public Education Campaign and Initial Adult COVID-19 Vaccination Uptake by Race and Ethnicity in the United States, 2020–2022*, Health Promotion Prac. (Dec. 30, 2023), https://doi.org/10.1177/15248399231221159; Elissa C. Kranzler, *Recalled Exposure to COVID-19 Public Education Campaign Advertisements Predicts COVID-19 Vaccine Confidence*, J. Health Comm. (Apr. 12, 2023), https://doi.org/10.1080/10810730.2023.2181891.

Tools Used to Track Americans' Attitudes Towards Vaccines

Tools	Description
Media Dose Dashboard Hub ("The Hub")	The Hub (described in more detail in Task 4) is a cloud-based, Tableau-type platform that tracks Campaign dissemination by component, creative, audience, and media channel; planned and actual impressions and gross ratings points (GRP); and for digital and social channels, viewability, clicks, click-through rate, and video completion rate. Other dashboards, such as the survey and web analytics dashboards, will help to provide key, timely insights to HHS and Team FMG to assess Campaign performance. The Hub, through its segmentation dashboard, will also map COVID-19 case and death burden, vaccination confidence and uptake, and distribution of comorbidities that increase risk of COVID-19 death.
Monthly Outcome Survey (MOS)	Team FMG will administer a series of cross-sectional, nationally representative surveys monthly to a probability-based panel of 7,500 (previously 5,000) U.S. adults to track awareness of and receptivity to the Campaign, adult vaccine confidence and uptake, and parental vaccine confidence and report of eligible child uptake. Team FMG has already designed the MOS, gained Institutional Review Board (IRB) and Office of Management and Budget (OMB) approvals, and implemented 11 waves since January 2021.
COVID-19 Attitudes and Beliefs Survey (CABS)	We will conduct a longitudinal survey of a nationally representative sample to assess change in 4-month increments on COVID-19 attitudes, beliefs, confidence, and vaccine uptake. Team FMG has already designed the CABS, gained IRB and OMB approvals, and implemented Waves 1–3 of the survey, and is uniquely positioned to continue implementation with no gaps.
Google Custom Search Dashboard	This dashboard is a non-public data source developed specifically for the Campaign by Google, in consultation with Team FMG, to assess designated market area (DMA)- and state-level changes in intent searches (denoting readiness to get vaccinated now) and consideration searches (queries about safety, side effects, effectiveness). Team FMG will assess relationships between Campaign dose and intent and consideration searches.
Experiments	We will use experiments to assess Campaign performance and inform tactical changes, such as A/B creative testing, brand lift studies, testing different targeting and optimization approaches, and assessing the influence of dosage levels on relevant searches or changes in belief agreement. These experiments are implemented both outside and within platforms such as Google or Facebook, taking advantage of their walled garden analytical capacity without sacrificing participant privacy.
Additional Tools	Team FMG will use publicly available data; social listening tools that monitor Twitter, Instagram, Facebook, Reddit, and other social media platforms to pull content in real time; media monitoring tools; and policy monitoring to assess the influence of policy on COVID-19 attitudes, beliefs, and behavior so we may account for the potential impact of these external influences in our evaluation models.

Source: Fors Marsh Group, Advancing VaccINTENT, FMG000538-539 (Dec. 30, 2021) (on file with Committee).

Tools	Description
Social Listening and Search Trends	FMG's social listening lab uses Brandwatch to examine relevant online conversations, their sentiment, and emergent themes in social media content and 90+ million websites. Team FMG's custom Google search dashboard provides detailed information about top COVID-19 vaccine-related trends, allowing us to assess key misconceptions and barriers to vaccine uptake and understand market-level changes in vaccine confidence. We will use insights gathered from social listening and search trends to anticipate upcoming trends in questions, concerns, or sentiment related to vaccines.
Weekly Situation Briefing	This weekly briefing will compile relevant insights from secondary research, publicly available surveys (e.g., Kaiser Family Foundation, Census Bureau, Ipsos), news articles, and academic literature. This briefing will also identify key signals from the segmentation, social listening, and search term insights to anticipate emergent trends. The briefing will provide important context to primary research efforts and situational awareness to all Campaign activities.
Formative Qualitative	Each quarter, one qualitative study (e.g., focus groups, in-depth interviews, dyads) will be conducted, designed to best meet the objectives of the research. Participants will be recruited to represent key vaccine hesitant audiences, and sessions will be conducted in participants' preferred language (with live translation provided as needed). Discussions will focus on barriers and motivators to vaccine uptake. These studies may also be used to test strategic message concepts or collect feedback on creative materials, as appropriate.
Evaluation Surveys	Described in Task 1f, the MOS and the CABS will capture findings on target audiences' behaviors, attitudes, and barriers to vaccination. These data will be overlaid with our segmentation model to enhance value while directly informing Campaign strategy. We will also leverage this survey data for additional analyses (e.g., latent class cluster analyses) to develop a more nuanced understanding of vaccine hesitancy.

Source: Fors Marsh Group, VacciNation Forward, FMG000520 (Jul. 16, 2021) (on file with Committee).

The Movable Middle

FMG's paid media strategy specifically targeted a subset of the population termed "the movable middle."[357] As applied to the Campaign, FMG described the movable middle as vaccine-hesitant Americans who had not yet decided whether to get a COVID-19 vaccine, as well as those who are part of hard-to-reach populations, or those actively seeking trusted information on vaccines. During the Campaign, the audience segments, which comprised the movable middle, changed based on population level data pertaining to vaccine uptake. To identify this group, FMG studied and categorized people based on demographics, such as age, ethnicity, life stage (e.g., parents of school-aged children), and location information (such as state and zip code). FMG's online advertising strategy for these groups aimed to "layer demographics with digital behaviors, such as frequently consumed content[,] . . . identify the optimum media mix via comprehensive quantitative (editorial, contextual relevance) and qualitative (reach, frequency, efficiency) analysis of available media vehicles."[358]

In an attempt to target and sway vaccine hesitant populations, FMG created audience "personas" that represented how target audiences experienced the pandemic and tried to identify which messages had the most potential to motivate them.[359] The personas were developed based on information gathered through national geographic segmentation tools.[360] FMG also used "journey mapping activities" to target vaccine hesitant populations. According to FMG documents, journey mapping activities involved "a simulated day-in-the-life analysis . . . to assess our target audience's interaction with media, organizations, and trusted messengers in ways that get closest to actual observations and provide deeper insights than secondary data sets could alone."[361]

Additionally, FMG used its public opinion surveys to monitor and track key information on vaccine hesitant parents. According to documentation obtained by the Committee, FMG "proactively proposed including the following elements in survey tools: monitoring of parental vaccine hesitancy, parental reporting of eligible child vaccine uptake, and booster uptake."[362]

Meanwhile, FMG's Preparing the Nation (PTN) strategy focused on answering emerging questions about COVID-19 vaccines to decrease vaccine skepticism and correct misinformation.

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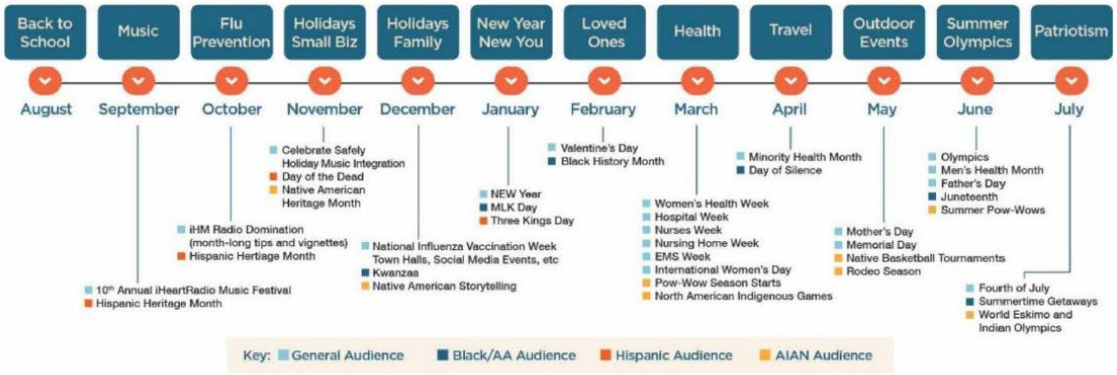
[357] The Movable Middle is a marketing term used of the most responsive target audience for a brand. Movable middles are "defined by having a mid-range probability of buying an advertised brand; they are proven mathematically to have five times the responsiveness to that brand's advertising. They are unique to each brand. While they overlap somewhat with heavy buyers, they also include medium, light, and non-buyers. This helps marketers not only achieve good returns, but also expose their brand to a larger group of receptive consumers for long-term growth." *See Movable Middles Growth Framework*, MMA, https://www.mmaglobal.com/movable-middles.
[358] Fors Marsh Group, VacciNation Forward, FMG000524 (July 16, 2021) (on file with Committee).
[359] Fors Marsh Group, VacciNation Forward, FMG000522 (July 16, 2021) (on file with Committee).
[360] Fors Marsh Group, VacciNation Forward, FMG000522 (July 16, 2021) (on file with Committee).
[361] Fors Marsh Group, Advancing vaccINTENT, FMG000542 (Dec. 30, 2021) (on file with Committee).
[362] Fors Marsh Group, Advancing vaccINTENT, FMG000539 (Dec. 30, 2021) (on file with Committee).

The PTN team closely collaborated with HHS officials to "regularly synthesize findings from Google search trends and monitor social listening tools, [weekly reports, trackers,] to recommend, develop, shepherd through clearance, and traffic a range of timely static and video ads, including paid search and paid social ads, on platforms such as Facebook, Instagram, Twitter, Pinterest, Reddit, YouTube, Google, and Bing."[363]

FMG established a media calendar to "augment and amplify earned, social, and paid media exposure with compelling messaging in a pre-planned schedule of activities."[364] Some of these revolved around key holidays, milestones, and major events targeted at different communities and demographics. For example, FMG targeted Chinese Americans with ads around the Lunar New Year. The Campaign also targeted parents and students with ads promoting vaccination before spring break and summer camp.[365] These Campaign ads were designed to "look and feel like part of the same family, serve multiple purposes, and be optimized, upcycled, or made more 'snackable' as needed."[366]

Sample Media Calendar



Source: Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000508 (Aug. 14, 2020) (on file with Committee).

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[363] Fors Marsh Group, Advancing vaccINTENT, FMG000550 (Dec. 30, 2021) (on file with Committee).
[364] Fors Marsh Group, Uniting a Resilient Nation COVID-19 Public Health and Reopening America: Public Service Announcements and Advertising Campaign, FMG000508 (Aug. 14, 2020) (on file with Committee).
[365] U.S. Department of Health and Human Services, *Happy Lunar New Year*, YouTube (Jan. 18, 2023), https://www.youtube.com/watch?v=LZNW763RowQ&list=PLrl7E8KABz1Gu7vZBriyrHs93xnXTrIDa&index=24 (content removed by HHS. No longer publicly available as of June 2024); U.S. Department of Health and Human Services, *Get Ready for Spring Break - :15,* YouTube (Mar. 17, 2022), https://www.youtube.com/watch?v=KIALpCi-Sf8&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=14 (content removed by HHS. No longer publicly available as of June 2024); U.S. Department of Health and Human Services, *Plan for Spring Break - :15*, YouTube (Mar. 17, 2022), https://www.youtube.com/watch?v=WSguYbM5xHo&list=PLrl7E8KABz1Feb8FvDwlIiPkAhhn-taA7&index=2 (content removed by HHS. No longer publicly available as of June 2024); U.S. Department of Health and Human Services, *COVID Vaccines Make Summer Camp Safer - :15,* YouTube (Apr. 21,2022), https://www.youtube.com/watch?v=T4xAMW1zHbE&list=PLrl7E8KABz1Gu-X9znwaEPHplHRjSWRpR&index=11 (content removed by HHS. No longer publicly available as of June 2024).
[366] Fors Marsh Group, Advancing vaccINTENT, FMG000549 (Dec. 30, 2021) (on file with Committee).

The scale of the public relations campaign raises serious questions over further entrenching Big Tech's role in surveilling Americans and in seeking to influence public opinion. Without more answers from Google and HHS, it is unclear whether personally identifiable information was in any way used by Google in the development of the Campaign for the custom search dashboard, and to what extent children's viewing habits were involved in the Campaign. Google, like other Big Tech companies, has been able to bury in their privacy policies what they do with Americans' information in the absence of a federal data privacy and security standard. Current data privacy protections have been limited to just minors under the age of 13.[367] Even with that limited privacy protection, Google and other Big Tech companies have been dogged for not doing enough to protect children online, and often, advertising targeted for adults has been fed to kids.[368]

Findings from Campaign Surveys

Data collection tools, including routinely administered surveys, sought to inform the Campaign's strategies by providing insight on the public's perceptions towards COVID vaccines and boosters, vaccine side effects, masking guidance, trust in government officials, misinformation, and other pertinent issues.[369]

Demographic Data Collection

The Campaign targeted certain population groups in their surveys and utilized population demographics, geographic characteristics, and political leanings to determine where to send their ads.[370] Information collected included vaccine hesitancy tendencies, parents' intent to vaccinate their children, and booster hesitancy. This data was then curated to develop ads for different groups based on political leanings and religious affiliations. For example, FMG provided HHS with survey results on vaccine and booster hesitancy, as well as perceived COVID risk among conservative, evangelical Christian, unvaccinated, and rural Americans. Some indicators were repeatedly surveyed (e.g., perceived COVID risk among conservatives, males, Whites, and the unvaccinated).

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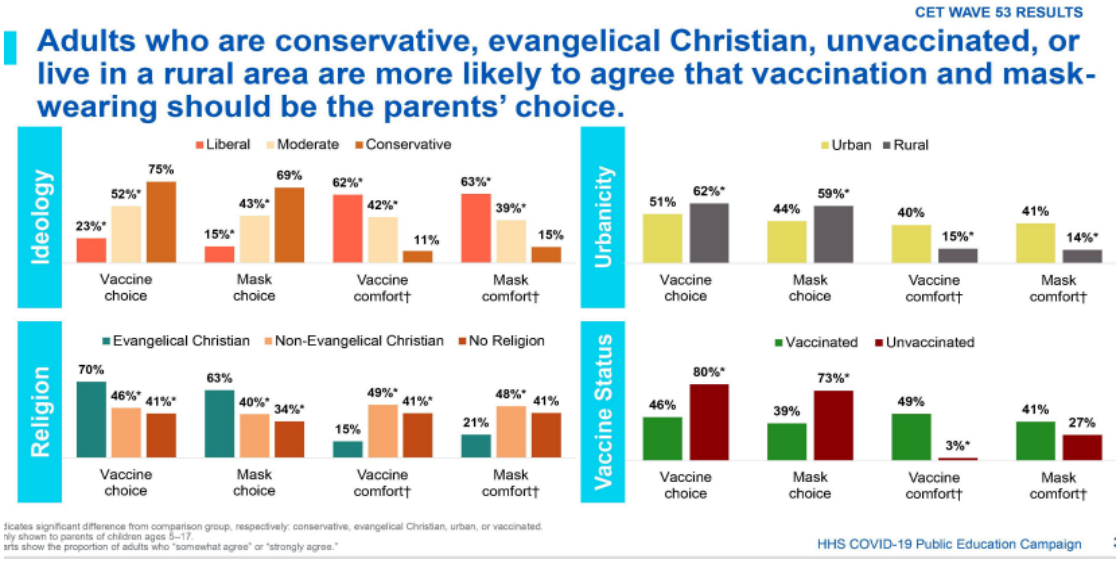
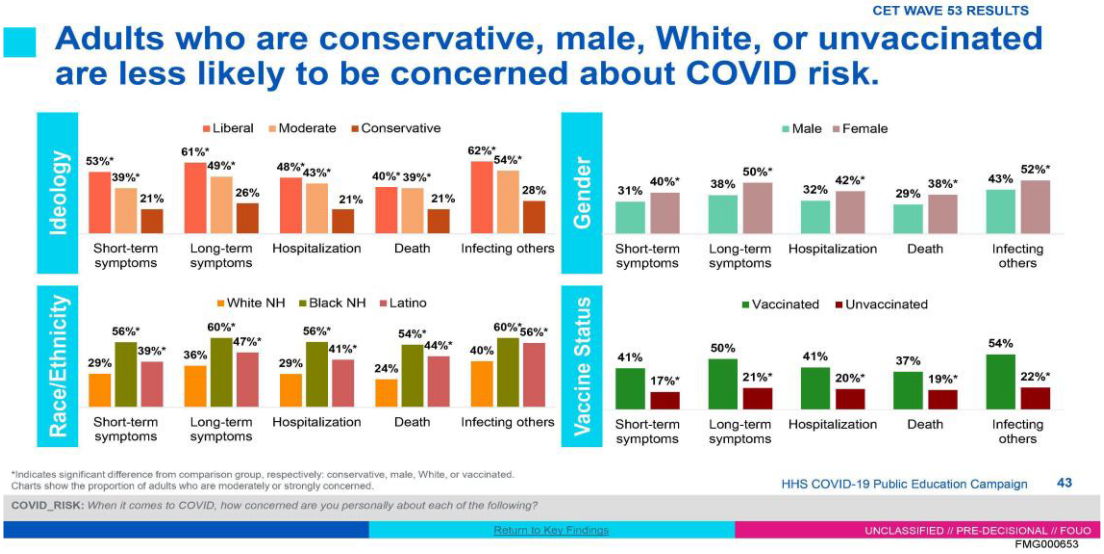
[367] 15 U.S.C §§ 6501-6506, Children's Online Privacy Protection Act (1998).
[368] Tonya Riley, *Senators Urge FTC Probe of Alleged Children's Privacy Violations by Google,* CyberScoop News (Aug, 17, 2023), https://cyberscoop.com/ftc-google-youtube-coppa-childrens-privacy/.
[369] Fors Marsh Group, VacciNation Forward, FMG000520 (July 16, 2021) (on file with Committee).
[370] Search results of HealthData.gov for "0\HHS COVID-", https://healthdata.gov/browse?category=Health&q=HHS+COVID- (last searched Dec. 14, 2023).

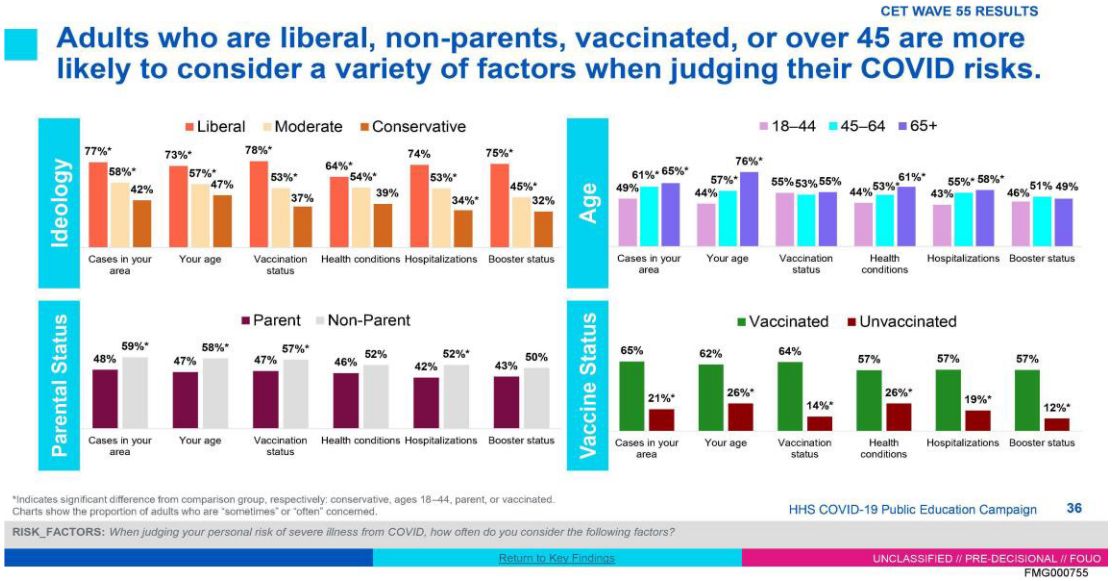
Demographic Data on Vaccine Attitudes, March—June 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 53 Results (March 11 – March 13, 2022), FMG000644 (on file with Committee).

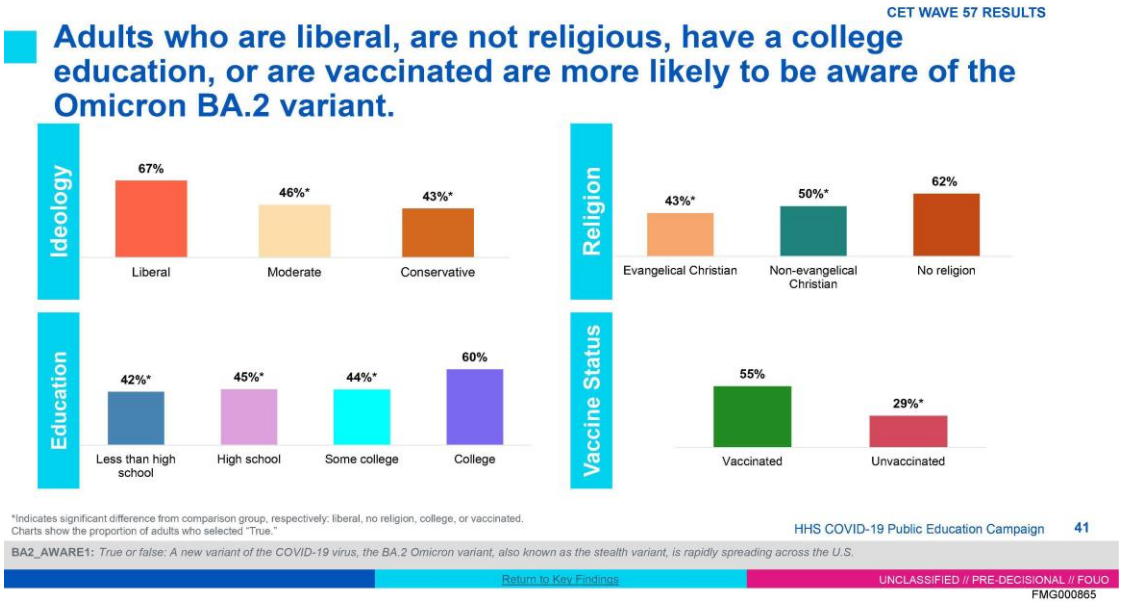


Source: Fors Marsh Group, Current Events Tracker: Wave 53 Results (March 11 – March 13, 2022), FMG000653 (on file with Committee).

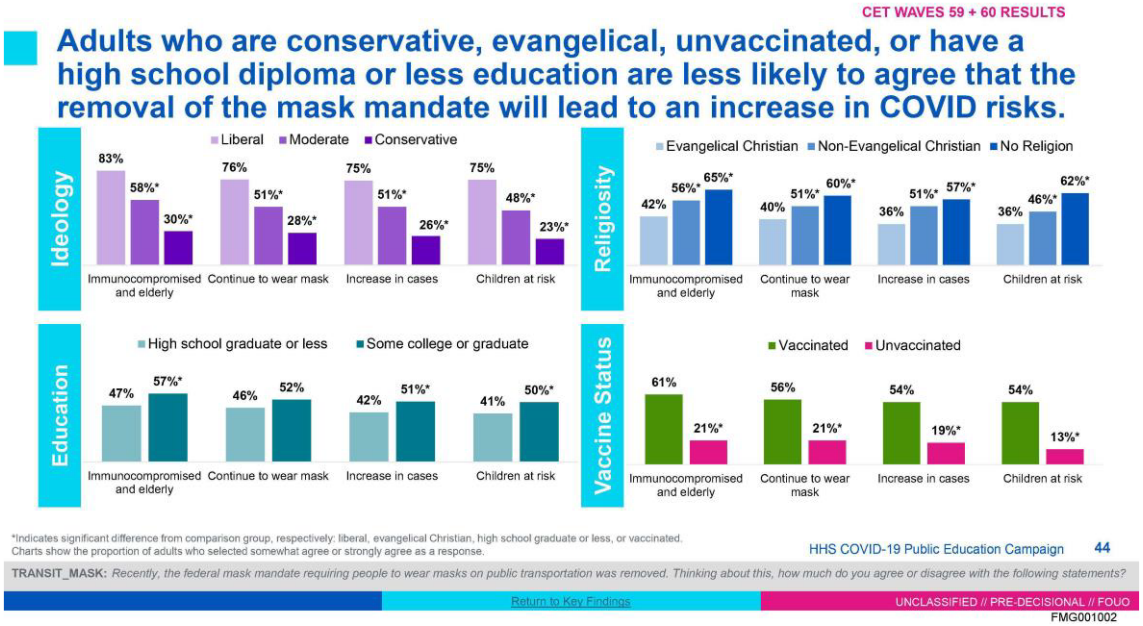


Source: Fors Marsh Group, Current Events Tracker: Wave 55 Results (March 25-27, 2022), FMG000755 (on file with Committee).

CONFIDENTIAL BUSINESS/PROPRIETARY INFORMATION

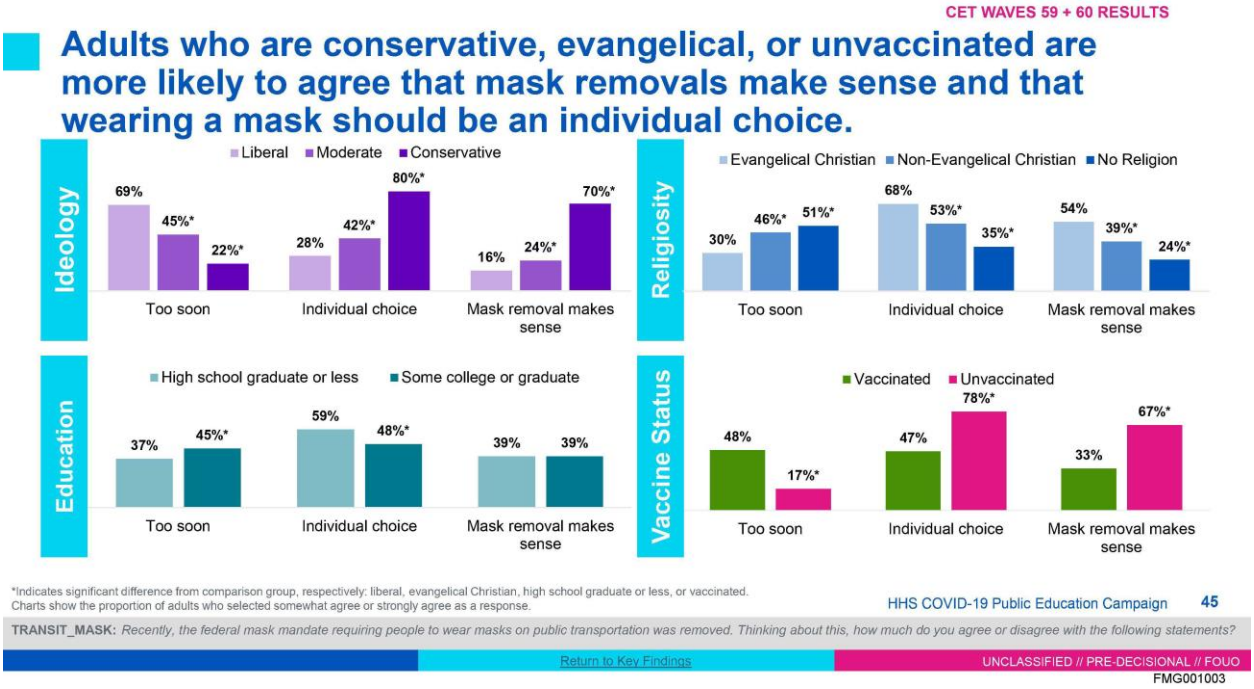


Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000865 (on file with Committee).

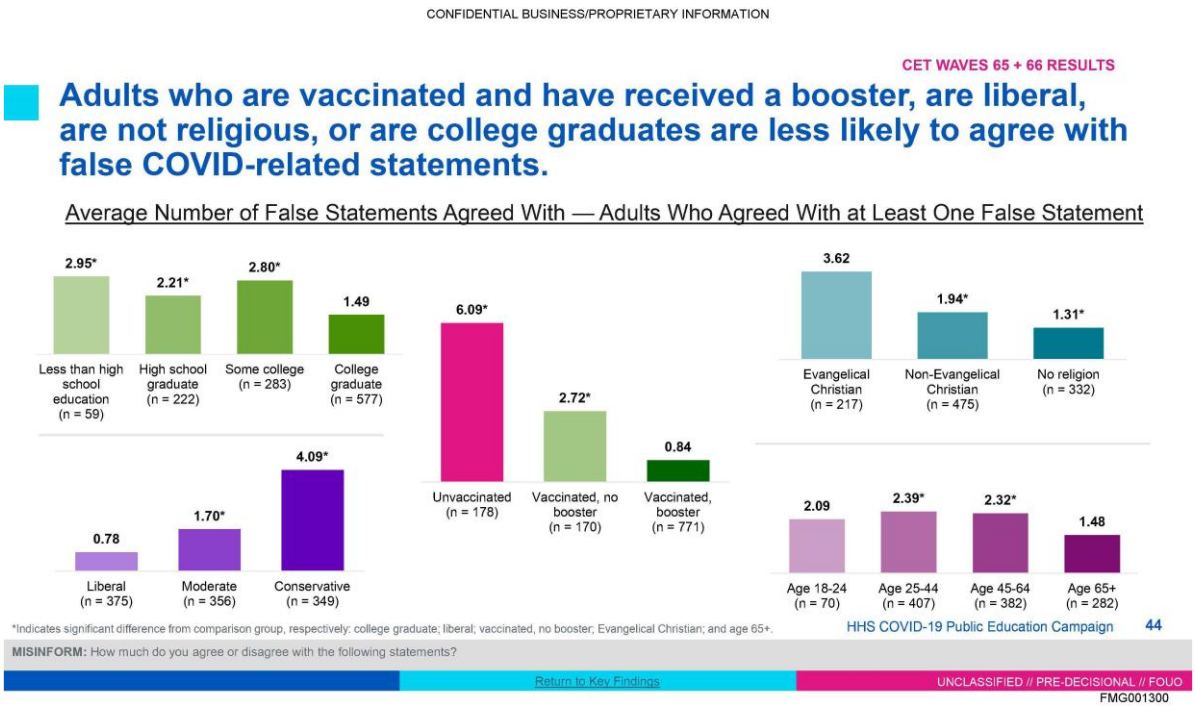


Source: Fors Marsh Group, Current Events Tracker: Wave 60 Results (April 29-May 1, 2022), FMG001002 (on file with Committee).

CONFIDENTIAL BUSINESS/PROPRIETARY INFORMATION



Source: Fors Marsh Group, Current Events Tracker: Wave 60 Results (April 29-May 1, 2022), FMG001002 (on file with Committee).

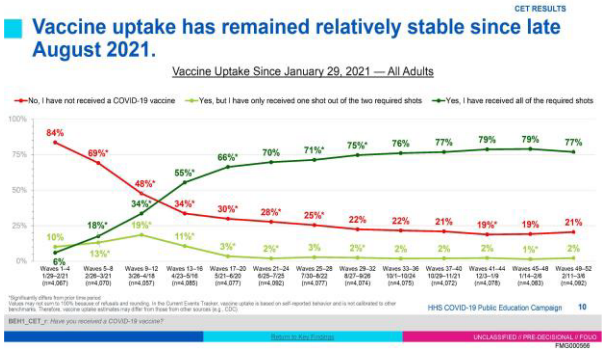


Source: Fors Marsh Group, Current Events Tracker: Wave 66 Results (June 17-19, 2022), FMG001300 (on file with Committee).

Vaccine Uptake and Readiness

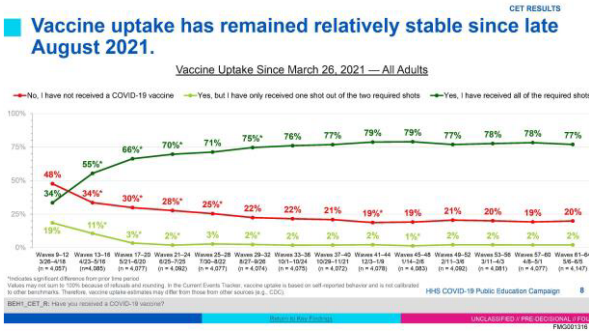
The Committee's review of survey results found, despite a comprehensive and expensive campaign, many Americans were largely unmoved in their opinions regarding CDC-recommended COVID-19 public health measures. Over and over, the Campaign's survey findings showed little to no change in vaccine uptake or readiness among the public. In spite of heavy promotion, findings reveal vaccine uptake remained unchanged for nearly a year between August 2021 and June 2022.

Vaccine Uptake, January 2021—March 2022



Source: Fors Marsh Group, Current Events Tracker Wave 52 Results, March 4-6, 2022, FMG000566 (on file with Committee).

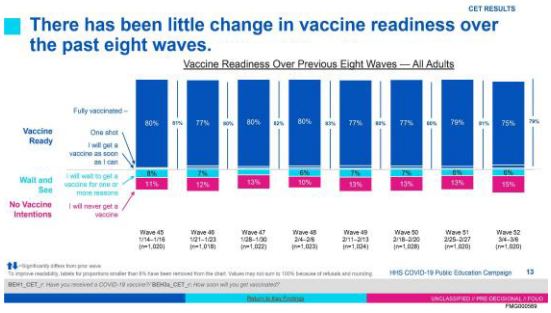
Vaccine Uptake, March 2021—June 2022



Source: Fors Marsh Group, Current Events Tracker Wave 67 Results, June 24-26, 2022, FMG001316 (on file with Committee).

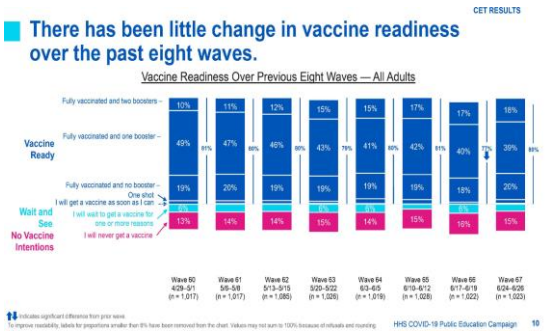
Similarly, survey results indicated there was little change in Americans' willingness to get vaccinated over at least a six-month period between January and June 2022.

Vaccine Readiness, January—March 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 52 Results (March 4 - 6, 2022), FMG000569 (Jul. 1, 2022) (on file with Committee).

Vaccine Readiness, April—June 2022

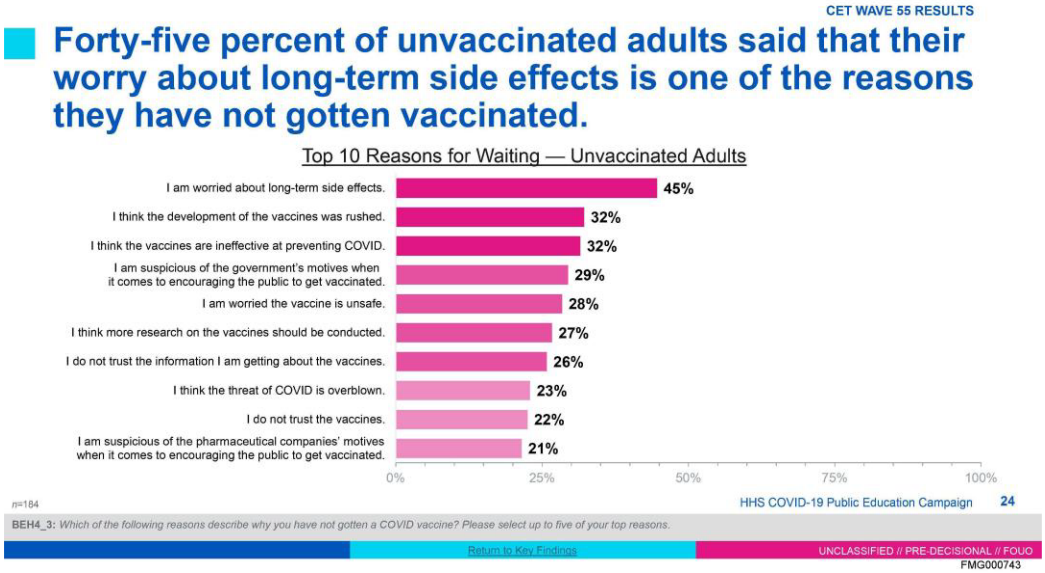


Source: Fors Marsh Group, Current Events Tracker: Wave 67 Results (June 24 - 26, 2022), FMG001318 (Jul. 1, 2022) (on file with Committee).

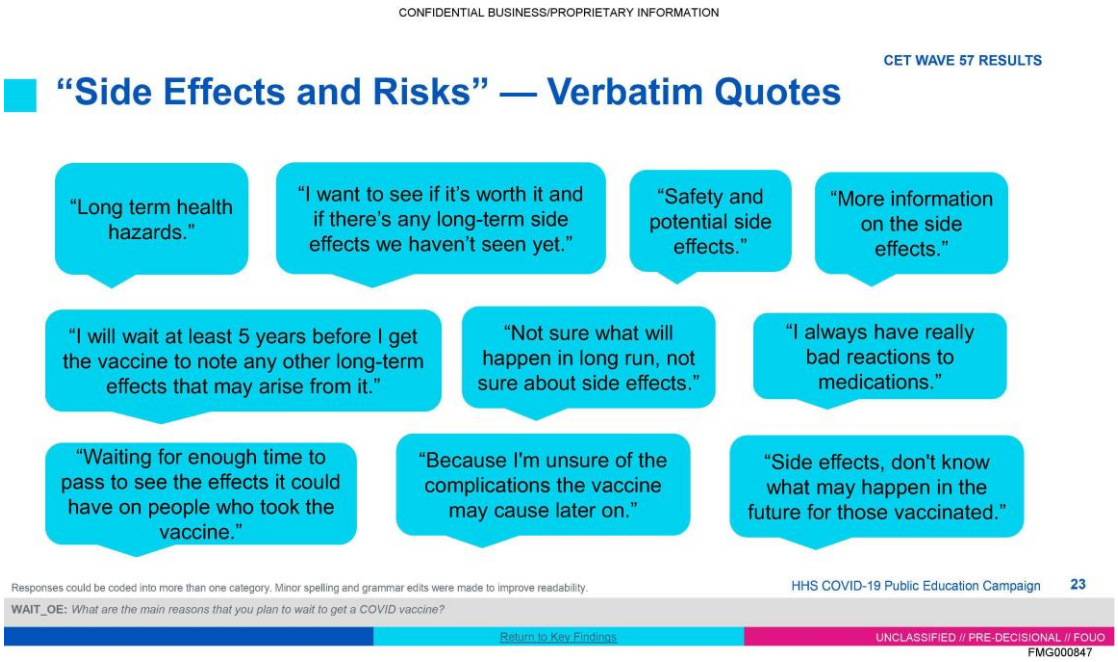
Among unvaccinated adults, nearly half of all those surveyed remained unvaccinated due to concerns about the long-term side effects of the vaccines.[371] Others remained concerned about the speed with which the vaccines were developed, their efficacy in preventing COVID infection and transmission, as well as mistrust of government motives in widely encouraging vaccines.

[371] Fors Marsh Group, Current Events Tracker: Wave 55 Results (March 25-27, 2022), FMG000743 (on file with Committee).

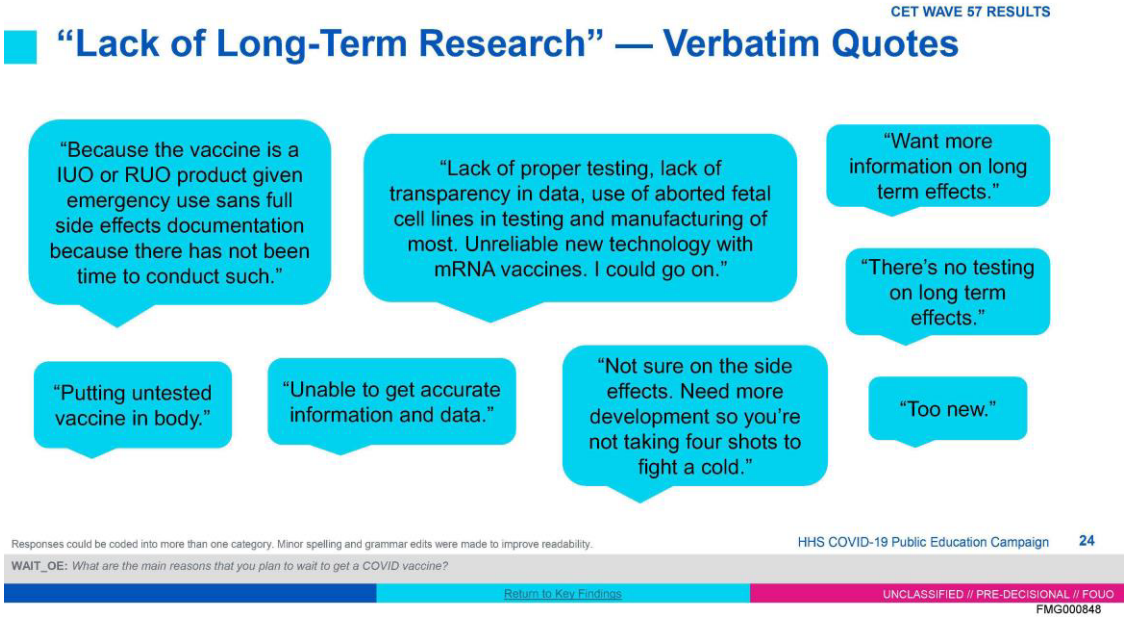
FMG Survey Results on Reasons for Vaccine Refusal Among Unvaccinated Adults



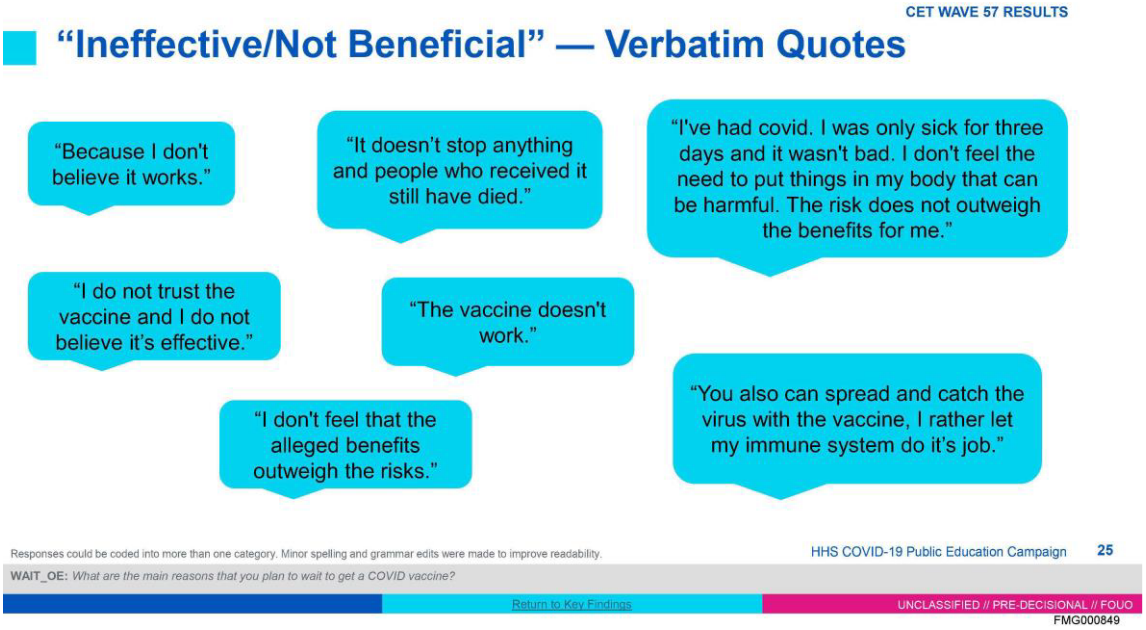
Source: Fors Marsh Group, Current Events Tracker: Wave 55 Results (March 25-27, 2022), FMG000743 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000847 (on file with Committee).



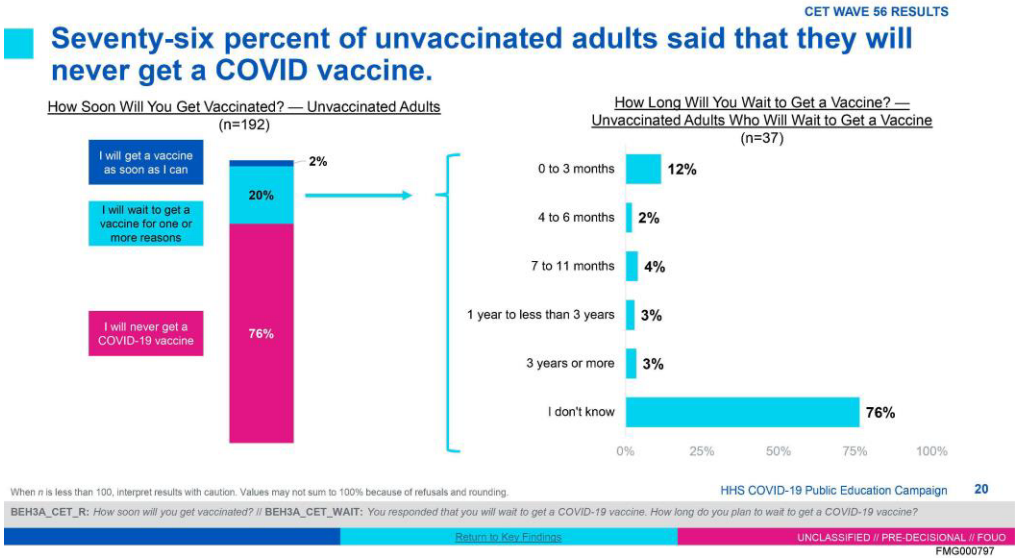
Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000848 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000849 (on file with Committee).

By April 2022, 76 percent of unvaccinated adults said they would never get a COVID vaccine.

Vaccine Readiness Among Unvaccinated Adults, April 2022

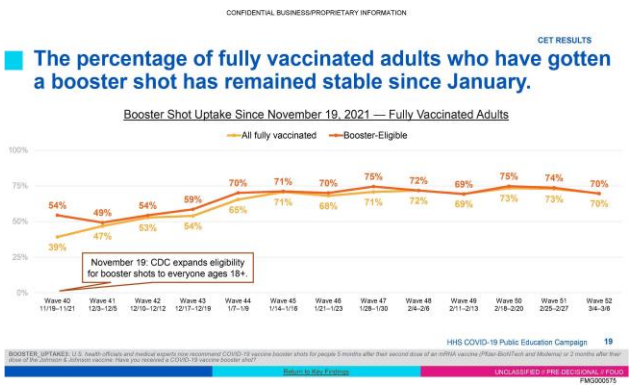


Source: Fors Marsh Group, Current Events Tracker: Wave 56 Results (April 1-3, 2022), FMG000797 (on file with Committee).

Booster Uptake

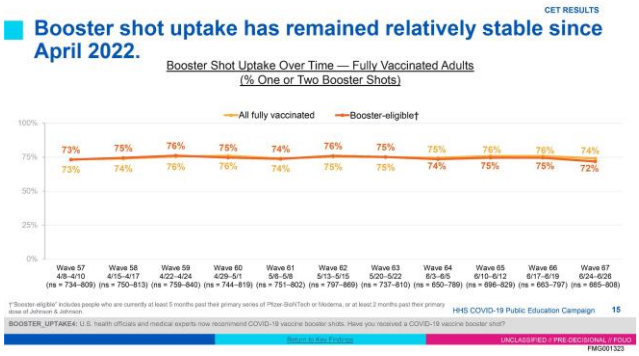
Survey findings between January and June 2022 also reveal no significant change in booster uptake among fully vaccinated adults.

Booster Shot Uptake, November 2021—March 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 52 Results (March 4-6, 2022), FMG000575 (Jul. 1, 2022) (on file with Committee).

Booster Shot Uptake, April—June 2022

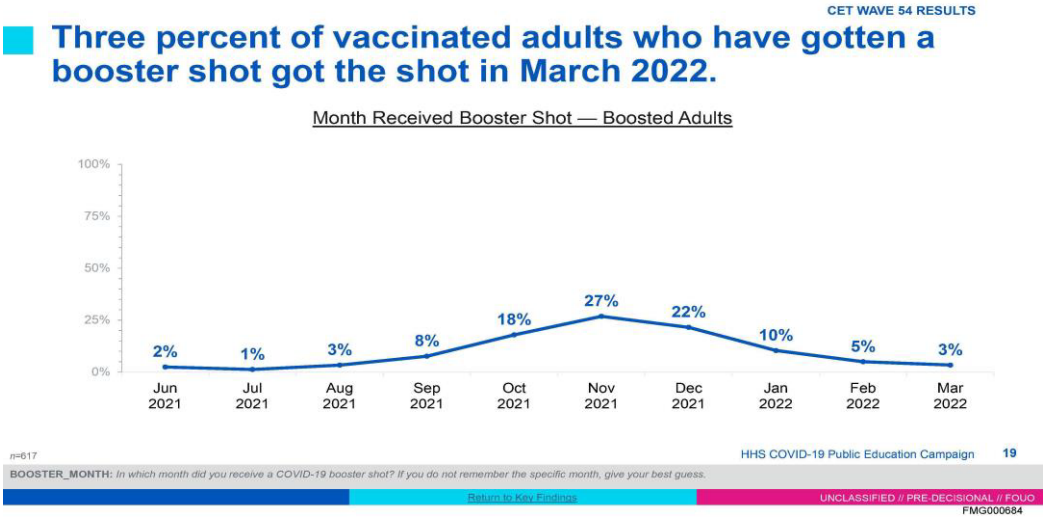


Source: Fors Marsh Group, Current Events Tracker: Wave 67 Results (June 24-26, 2022), FMG001323 (July 1, 2022) (on file with Committee).

Notably, survey findings also reveal that while the Campaign was ongoing, booster uptake peaked at 27 percent in November 2021 and gradually declined to 3 percent in March 2022.[372]

[372] Fors Marsh Group, Current Events Tracker: Wave 54 Results (March 18-20, 2022), FMG000684 (on file with Committee).

Booster Shot Uptake Among Vaccinated Individuals, March 2022

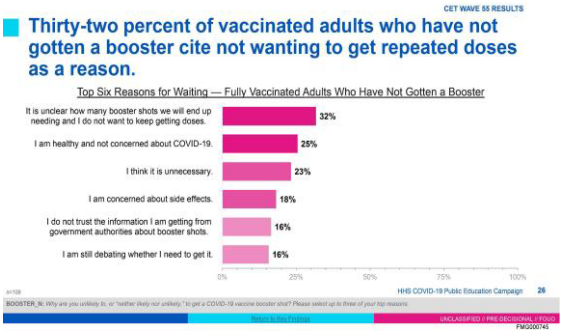


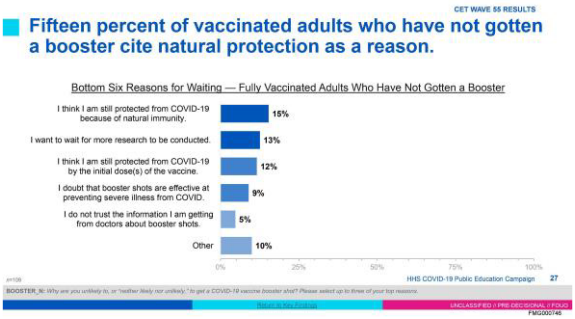
Source: Fors Marsh Group, Current Events Tracker: Wave 54 Results (March 18—20, 2022), FMG000684 (on file with Committee).

FMG survey results showed that among vaccinated adults, booster uptake rates slowed for various reasons. The vast majority of vaccinated adults who had refused a booster shot did so because they did not want to keep getting doses. Still others cited natural immunity from prior COVID infections. Around 50 percent of those surveyed agreed the public health community disagreed about the necessity of booster shots.[373] Around 40 percent of adults said the only way they would get a booster was if they were required to.[374]

[373] Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001221 (on file with Committee).
[374] *Id.*

Reasons for Booster Refusal Among Vaccinated Individuals, March 2022

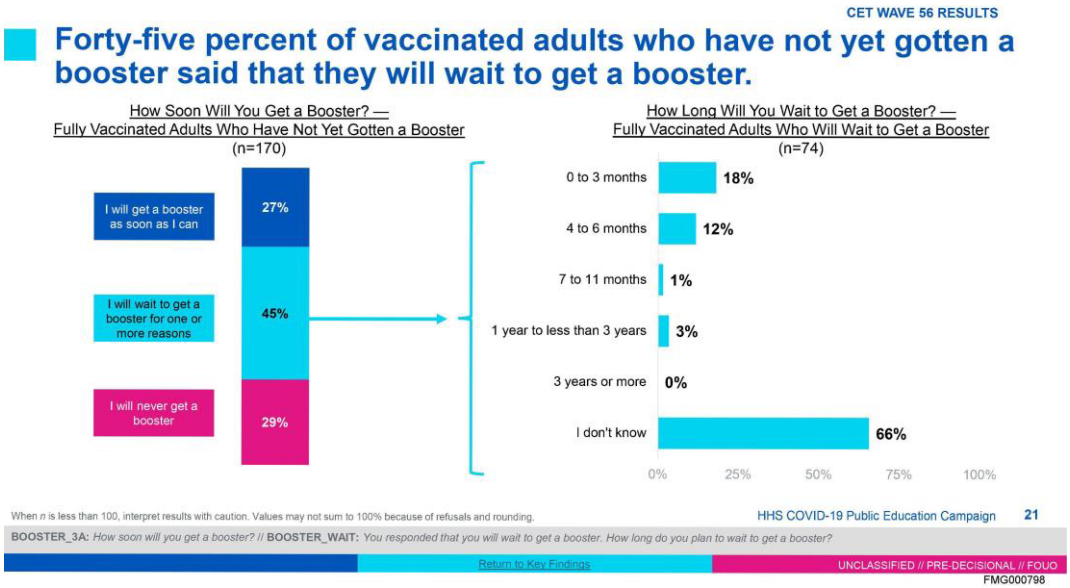




Source: Fors Marsh Group, Current Events Tracker: Wave 55 Results (March 25-27, 2022), FMG000745 (on file with Committee).

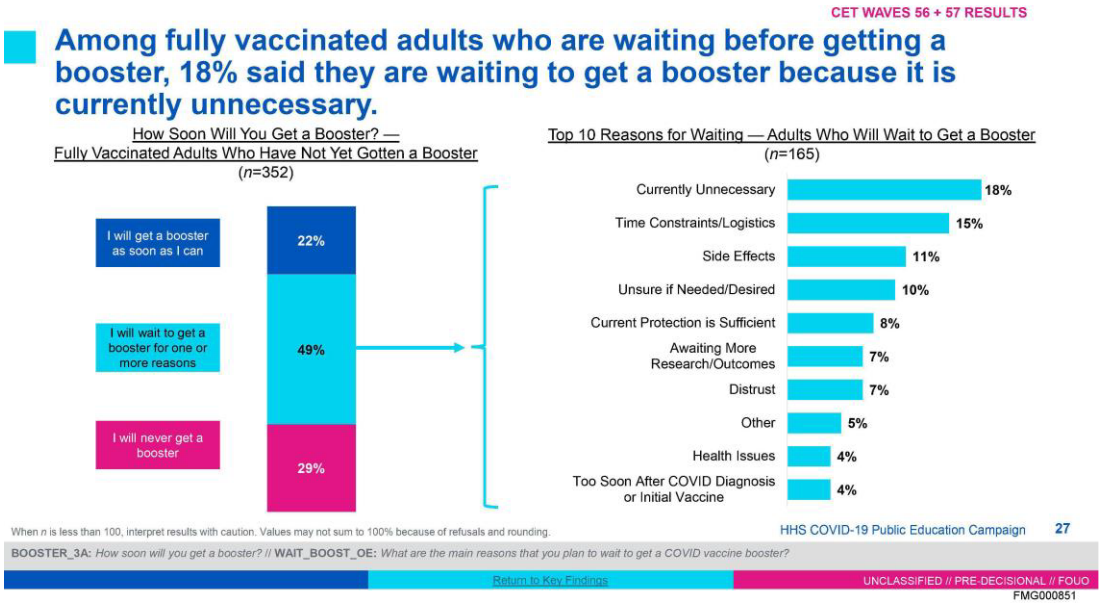
By April 2022, 45 percent of surveyed vaccinated adults who had not received a booster shot said they would wait to get a booster.

Vaccine Readiness Among Vaccinated Individuals, April 2022

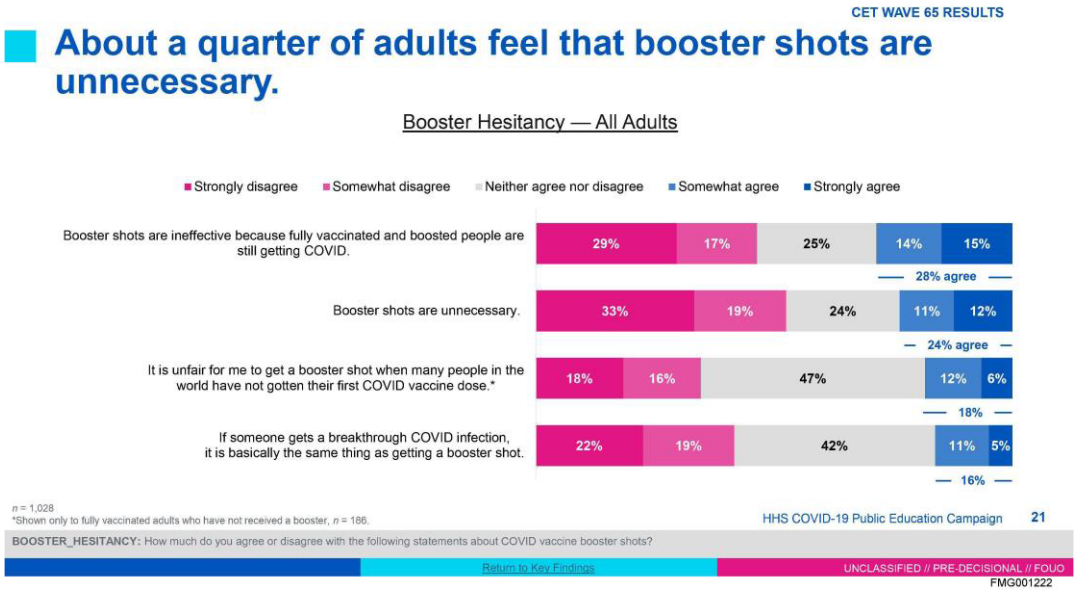


Source: Fors Marsh Group, Current Events Tracker: Wave 56 Results (April 1-3, 2022), FMG000798 (on file with Committee).

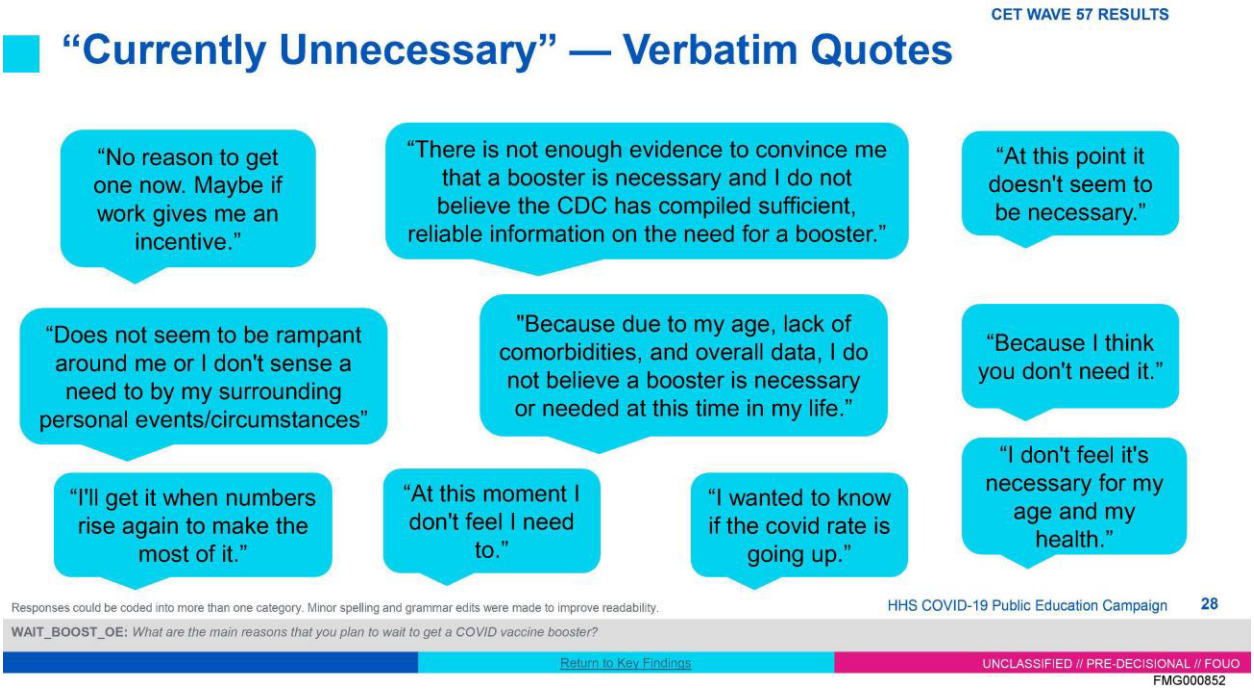
Among fully vaccinated adults who were waiting to get a booster, 18 percent of those surveyed said their reason for waiting was because they perceived the vaccine was "currently unnecessary."



Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000851 (on file with Committee).

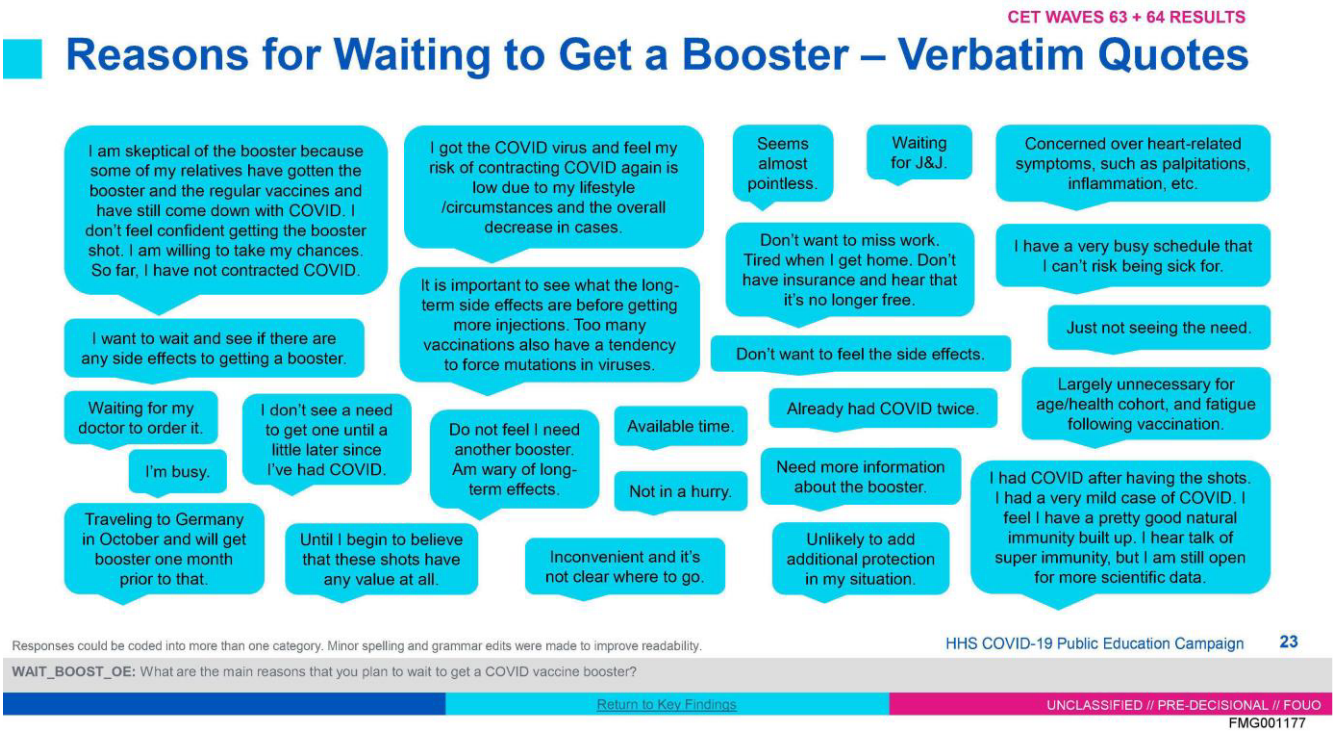


Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001222 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000852 (on file with Committee).

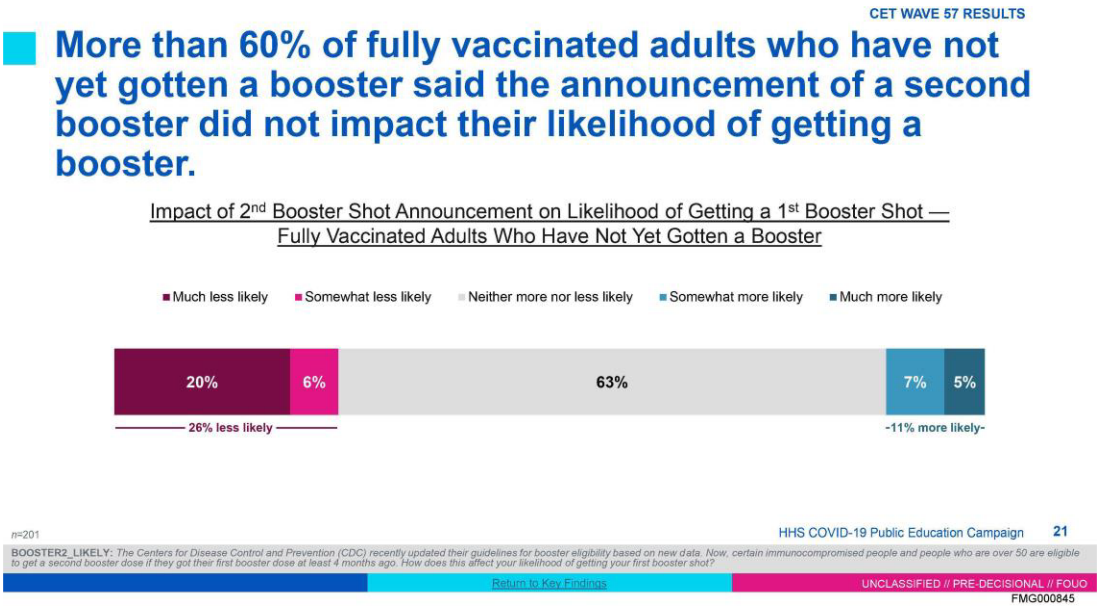
Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000854 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001177 (on file with Committee).

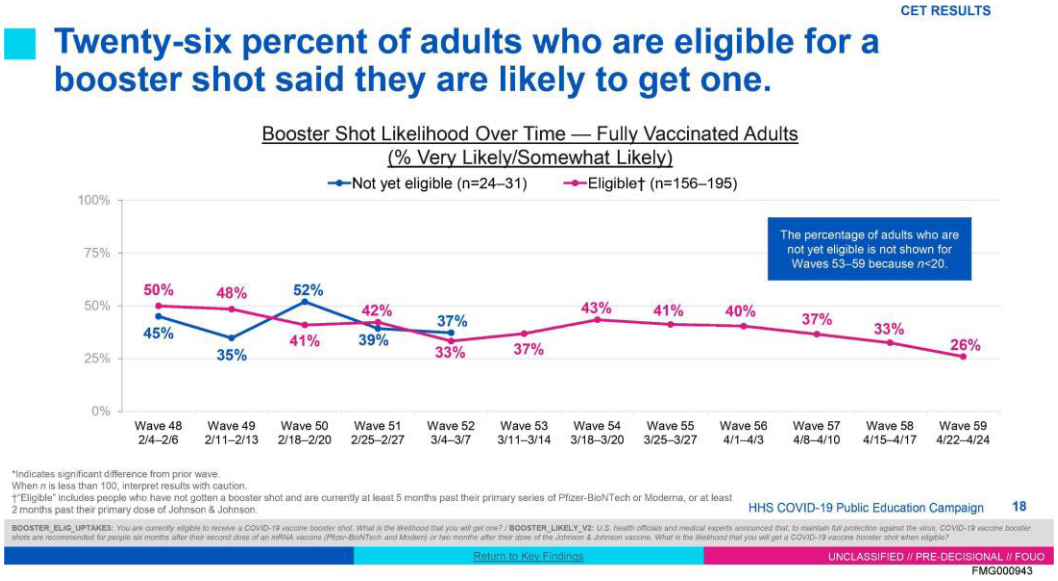
Following a second booster announcement, more than 60 percent of fully vaccinated adults who had not yet received a second booster shot stated the second booster announcement did not impact their likelihood of getting a booster.

<u>Impact of Second Booster Announcement on Vaccinated Individuals, April 2022</u>



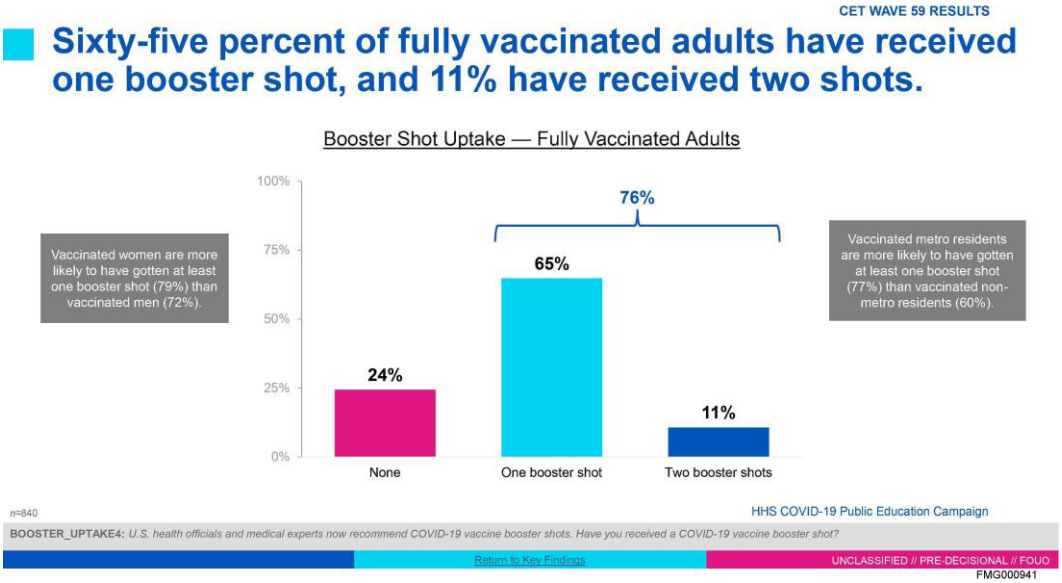
Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000845 (on file with Committee).

Even among those eligible for a second booster, 74 percent of surveyed adults stated they were unlikely to get a booster shot. Although there were minimal increases in booster uptake across survey periods, on average, the proportion of eligible adults who were unlikely to get a booster remained at over two-thirds of the surveyed population.



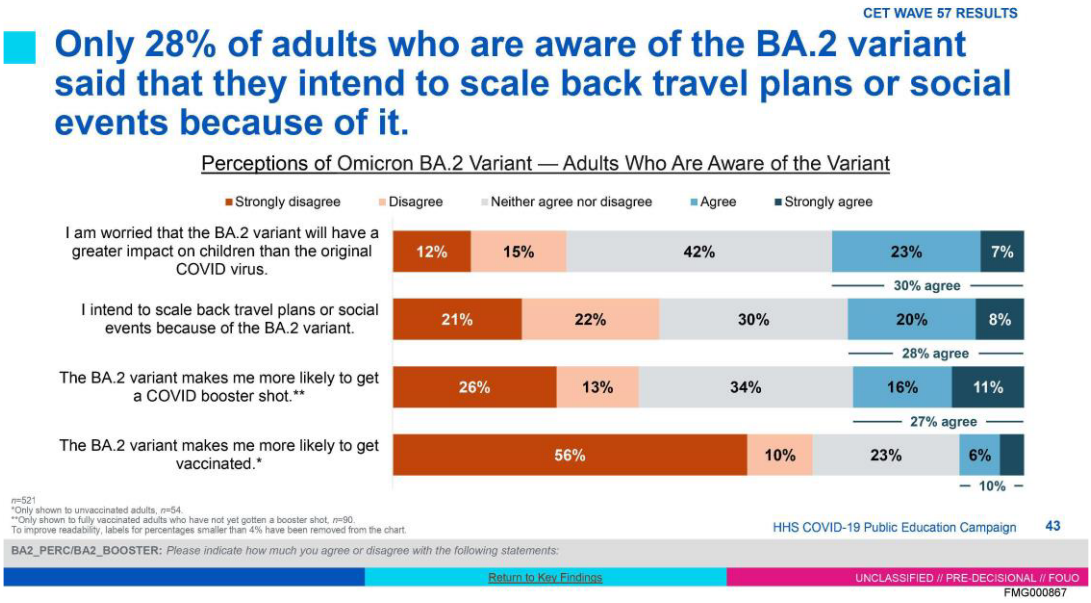
Source: Fors Marsh Group, Current Events Tracker: Wave 59 Results (April 22-24, 2022), FMG000943 (on file with Committee).

Although 65 percent of surveyed fully vaccinated adults had taken the first booster, only 11 percent had opted to receive a second booster.

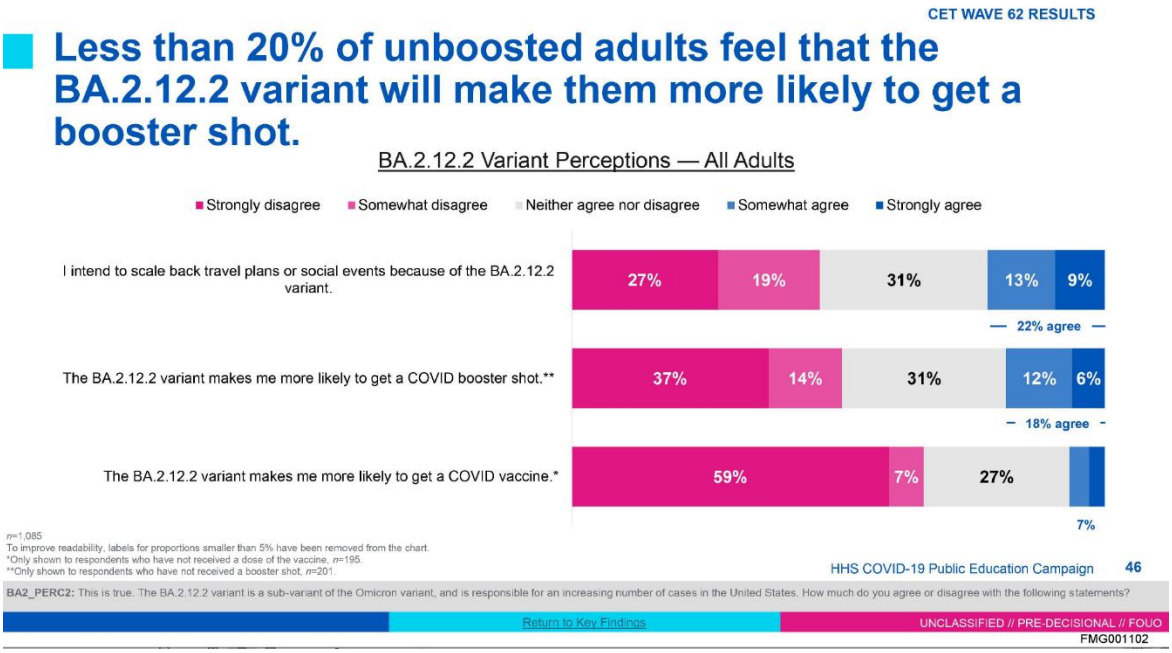


Source: Fors Marsh Group, Current Events Tracker: Wave 59 Results (April 22-24, 2022), FMG000941 (on file with Committee).

By the spring of 2022, survey results showed Americans were ready to get back to living—including traveling and attending social events—and a new COVID subvariant was not going to dampen their plans. Over two thirds of those surveyed stated the Omicron BA.2 variant did not make them more likely to get vaccinated. Nearly 40 percent of surveyed adults said the new variant did not make them want to get a COVID booster shot and an additional one third remained neutral. Over 43 percent of surveyed adults did not plan to scale back travel plans or social events.

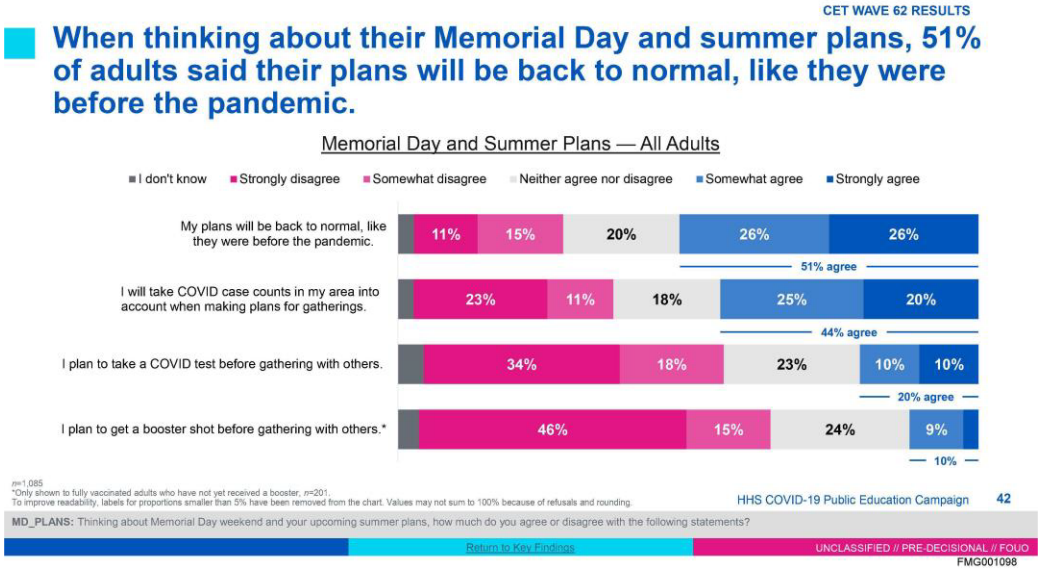


Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000867 (on file with Committee).



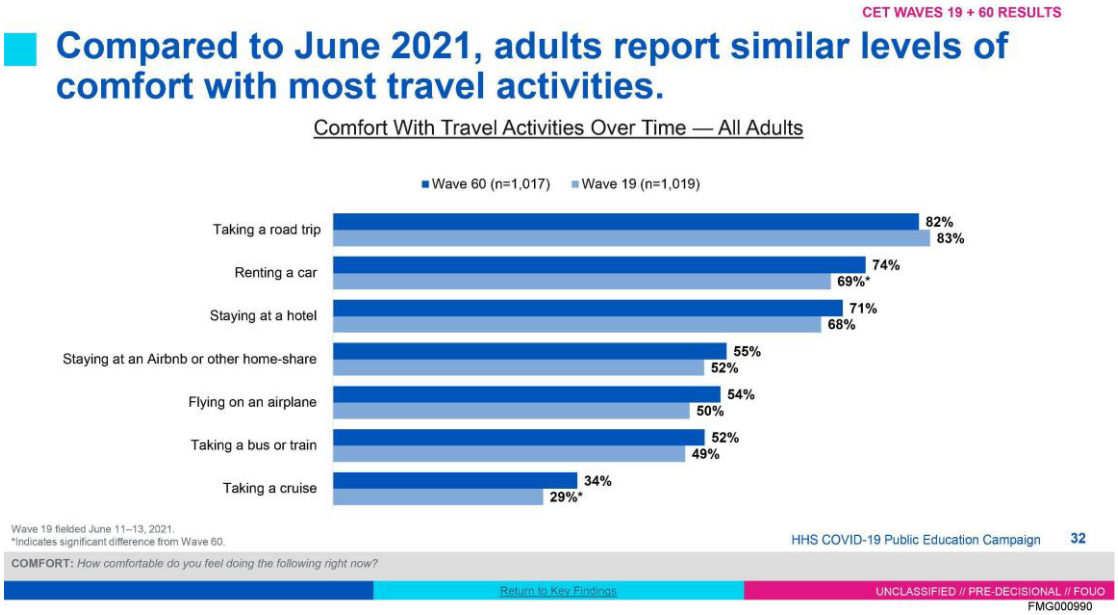
Source: Fors Marsh Group, Current Events Tracker: Wave 62 Results (May 13-15, 2022), FMG001102 (on file with Committee).

By May 2022, over 50 percent of surveyed adults indicated they would revert to pre-pandemic Memorial Day and summer plans. This included forgoing booster shots and COVID tests before gathering with others.



Source: Fors Marsh Group, Current Events Tracker: Wave 62 Results (May 13-15, 2022), FMG001098 (on file with Committee).

Interestingly, despite constantly emerging COVID subvariants, as well as state and federal travel restrictions, for nearly a year between June 2021 and May 2022, most adults reported similar levels of comfort with most travel activities.

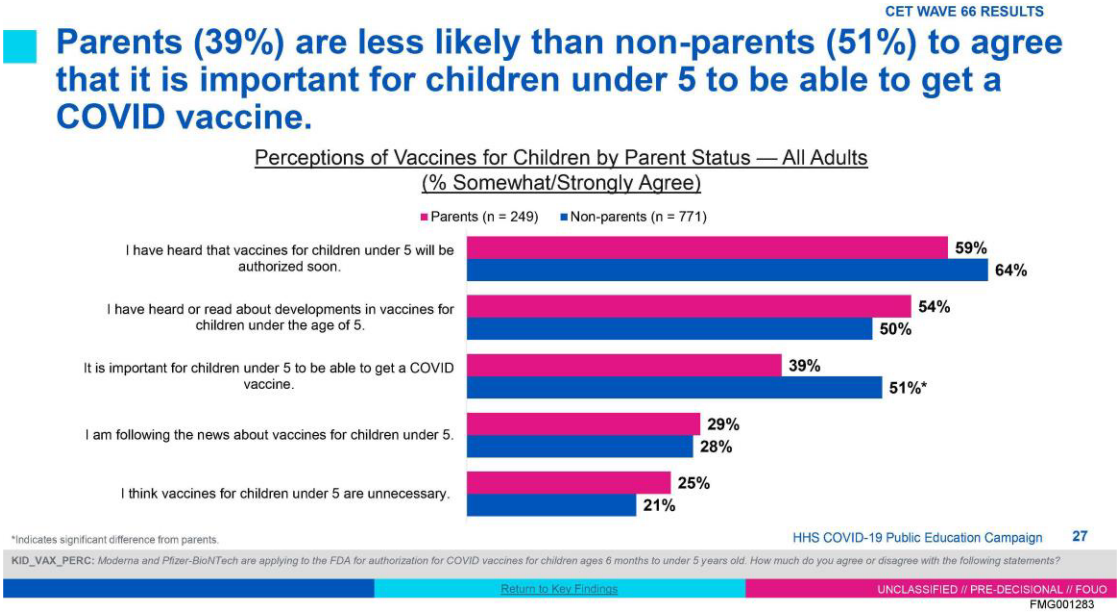


Source: Fors Marsh Group, Current Events Tracker: Wave 60 Results (April 29-May 1, 2022), FMG000990 (on file with Committee).

Child Vaccination and Boosters

The Campaign closely monitored vaccine hesitancy among the public, including among parents of children under 18 years. A CET survey finding from March 2022 showed between 60 and 76 percent of parents with unvaccinated children under 18 years were concerned about potential vaccine side effects.[375] At the same time, 53 percent of adults agreed that parents should be able to make their own choices about getting their children vaccinated, and as the COVID pandemic lagged, Campaign findings indicated a 20 percent drop in the number of adults who supported mask mandates in schools over a seven-month period.[376] Interestingly, school mask and vaccination mandates for teachers, staff, visitors, and students were most strongly supported by liberal, vaccinated adults, **non-parents** and those dwelling in urban areas.[377] In contrast, parents were more likely to agree that COVID vaccines for young children, especially those under 5, were unnecessary.

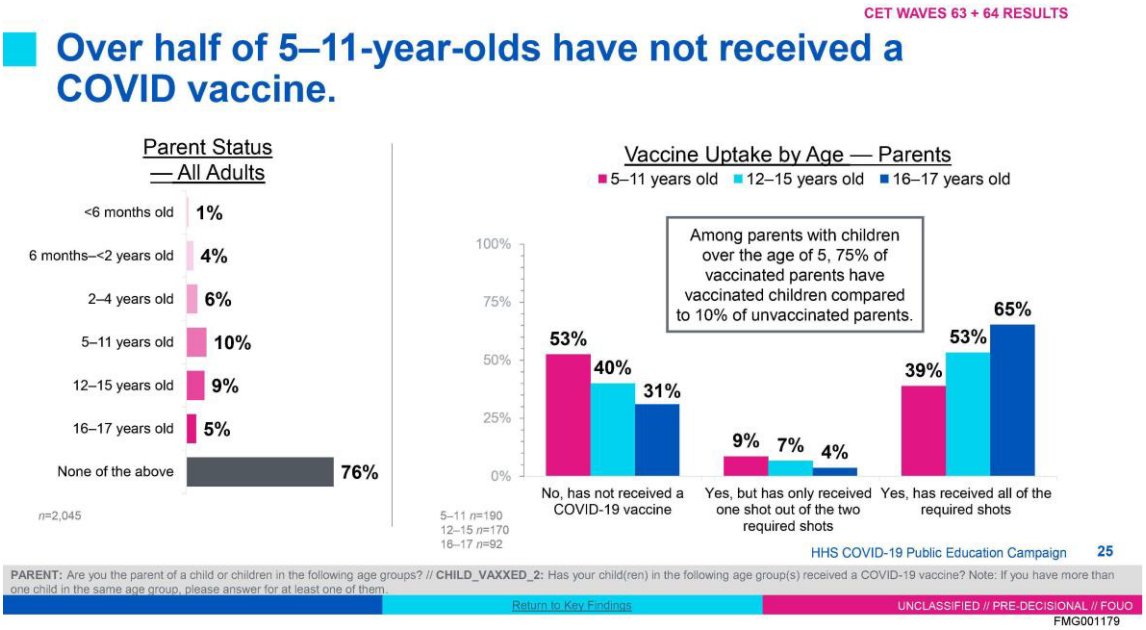
More Parents than Non-Parents Believe COVID Vaccines for Young Children are Unnecessary



Source: Fors Marsh Group, Current Events Tracker: Wave 66 Results (June 17-19, 2022), FMG001283 (on file with Committee).

[375] Fors Marsh Group, Current Events Tracker: Wave 52 Results (March 4-March 6, 2022), FMG000570 (on file with Committee).
[376] Fors Marsh Group, Current Events Tracker: Wave 53 Results (March 11-March 13, 2022), FMG000642-43 (on file with Committee.
[377] Fors Marsh Group, Current Events Tracker: Wave 53 Results (March 11-March 13, 2022), FMG000641 (on file with Committee.

In June 2022, over half of 5–11-year-olds had not received a COVID vaccine.

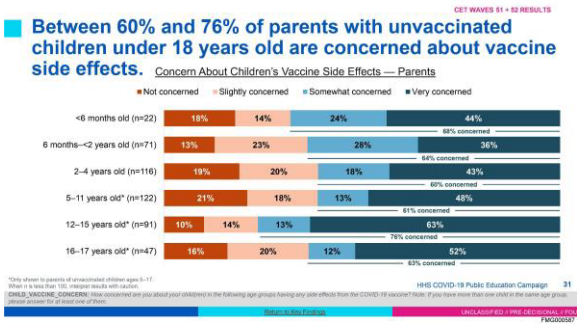


Source: Fors Marsh Group, Current Events Tracker: Wave 63 Results (June 3-5, 2022), FMG001179 (on file with Committee).

As the figure below indicates, in the spring of 2022 vaccine concerns among parents of unvaccinated children remained high.

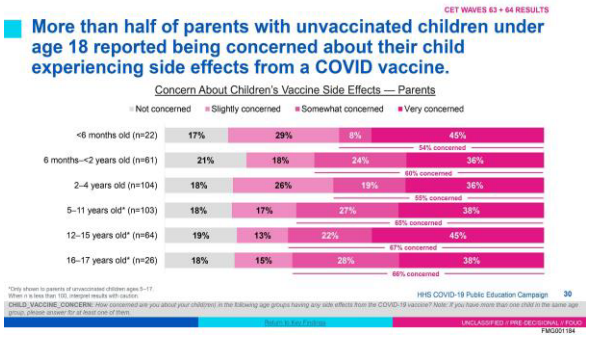
<u>Parental Concern on Potential Vaccine Side Effects to Children</u>

March 2022



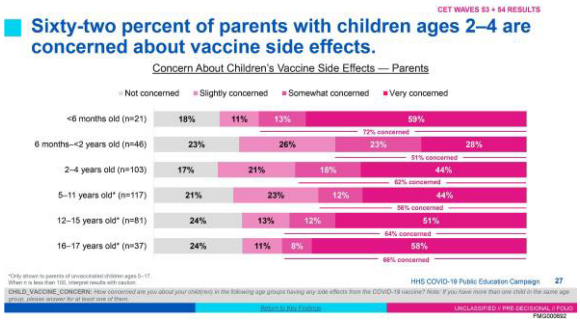
Source: Fors Marsh Group, Current Events Tracker: Wave 52 Results (March 4—March 6, 2022), FMG000570 (on file with Committee).

June 2022



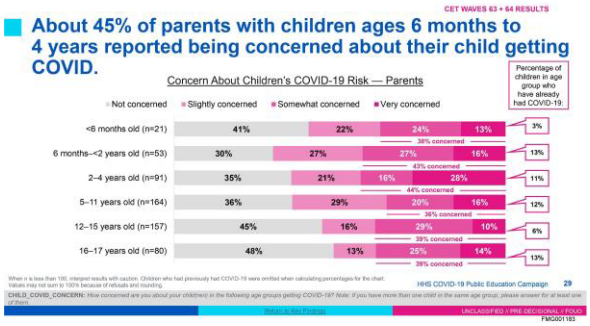
Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001184 (on file with Committee).

March 2022

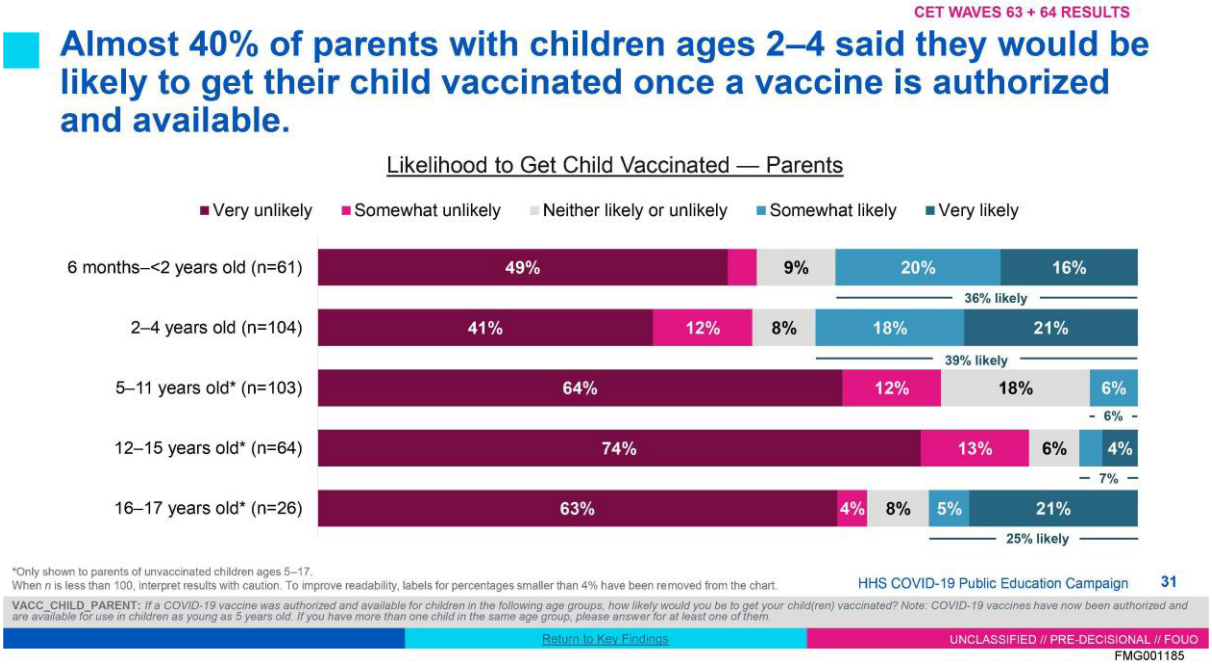


Source: Fors Marsh Group, Current Events Tracker: Wave 54 Results (March 18—20, 2022), FMG000692 (on file with Committee).

June 2022



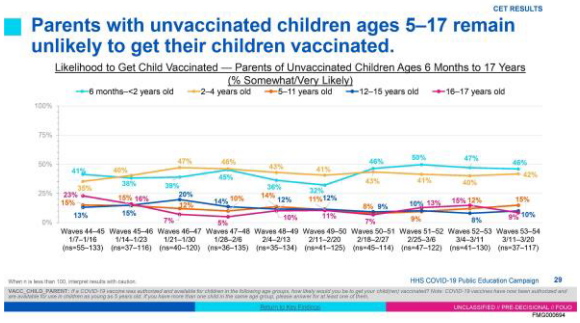
Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001183 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001185 (on file with Committee).

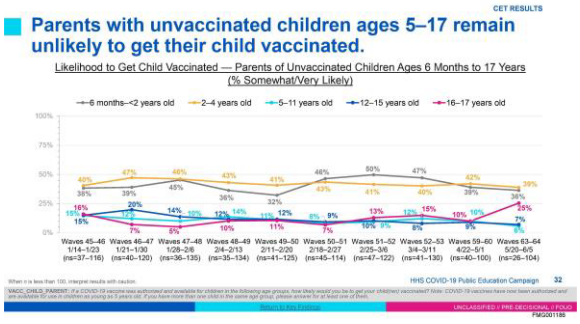
Parents of Unvaccinated Children Remain Firm in Decision to Not Vaccinate their Children

January—March 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 54 Results (March 18—20, 2022), FMG000694 (on file with Committee).

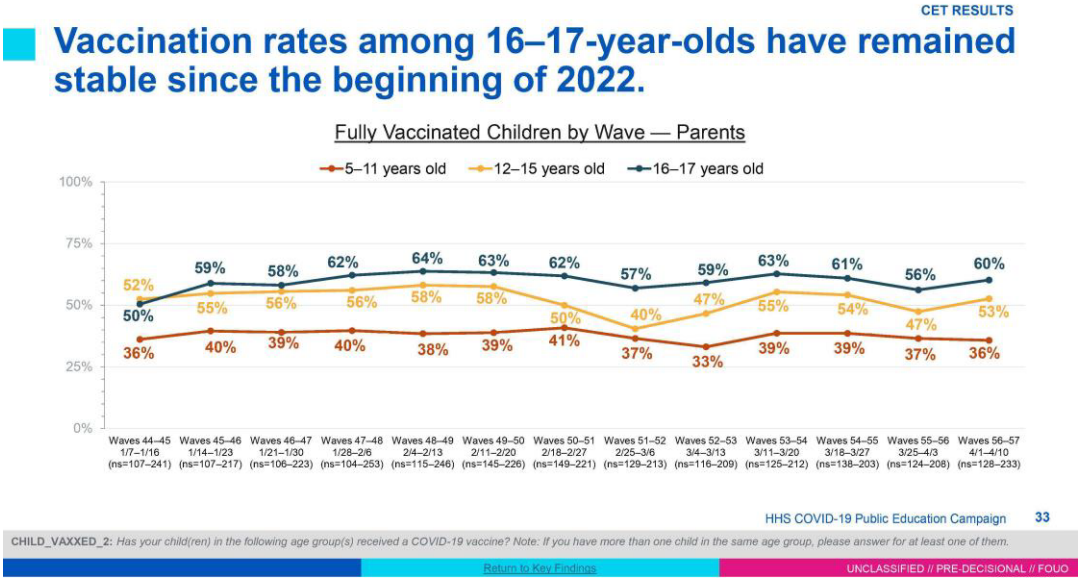
January—June 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001186 (on file with Committee).

By April 2022, vaccination rates among 16–17-year-olds had stabilized.

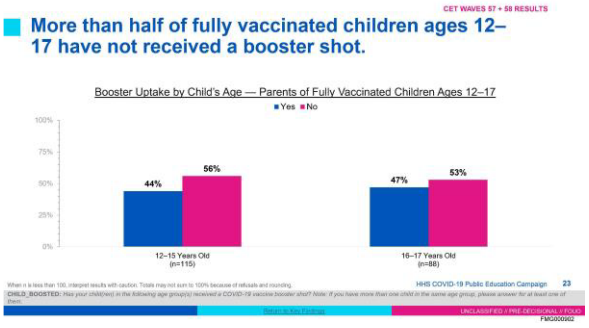
January—April 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000857 (on file with Committee).

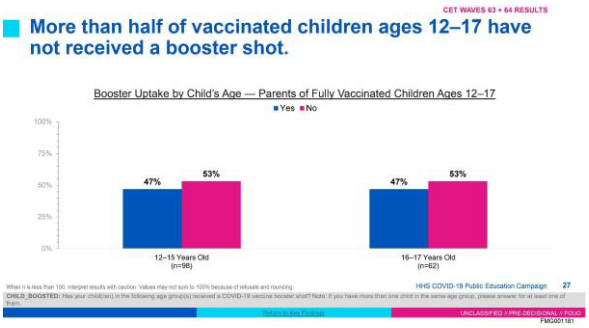
Moreover, more than half of fully vaccinated children 12-17 years old had not received a booster shot. This did not change as the months went on.

April 2022



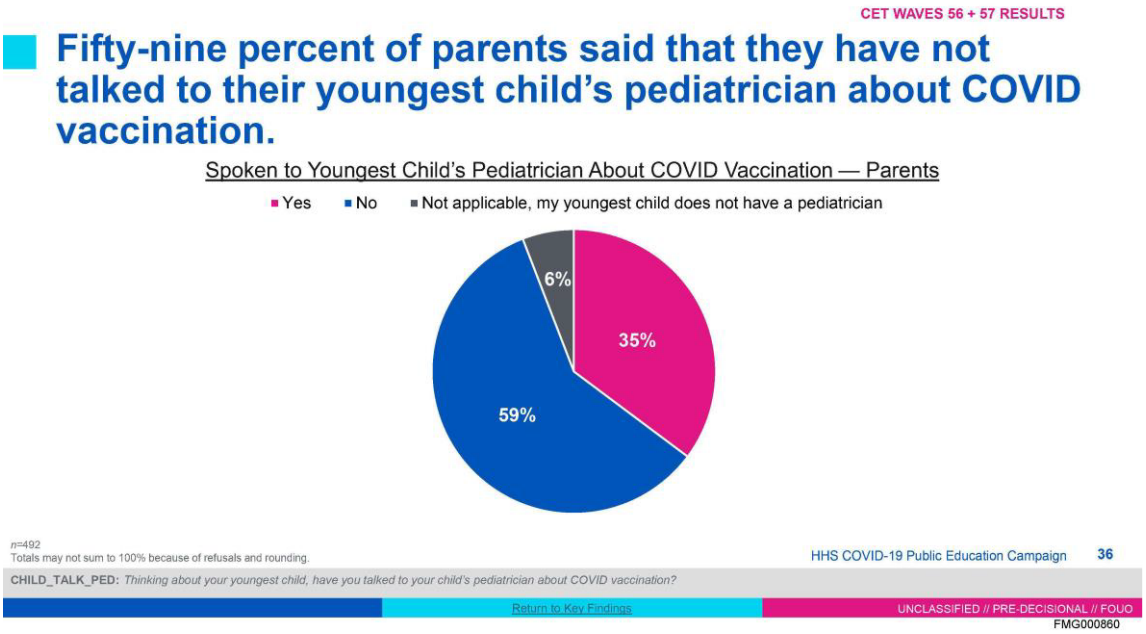
Source: Fors Marsh Group, Current Events Tracker: Wave 58 Results (April 15-17, 2022), FMG000857 (on file with Committee).

June 2022



Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001181(on file with Committee).

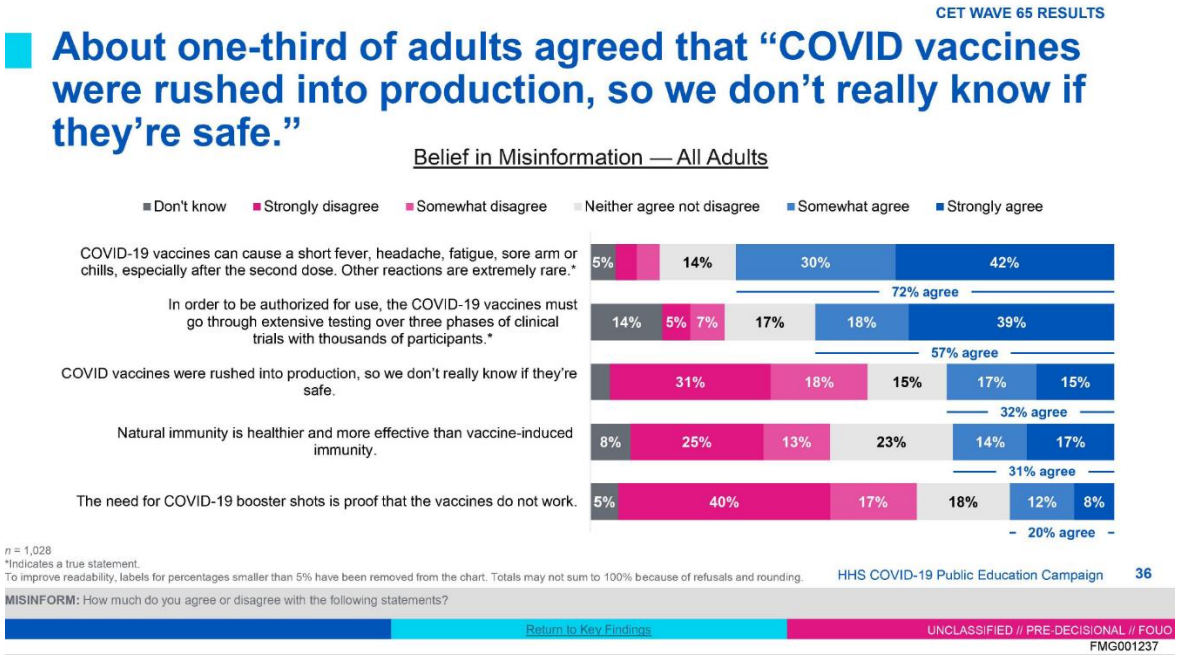
Furthermore, nearly two-thirds of surveyed parents had not spoken to their youngest child's pediatrician about a COVID vaccine, which presumably indicates this was a low priority for most parents with young children.



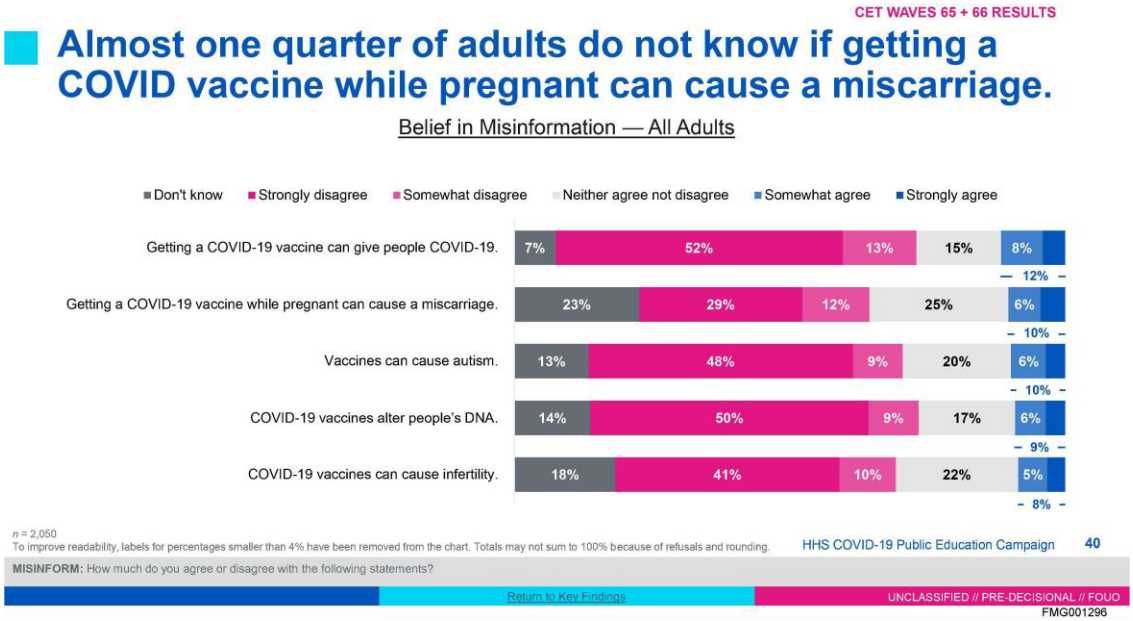
Source: Fors Marsh Group, Current Events Tracker: Wave 57 Results (April 8-10, 2022), FMG000860 (on file with Committee).

Misinformation

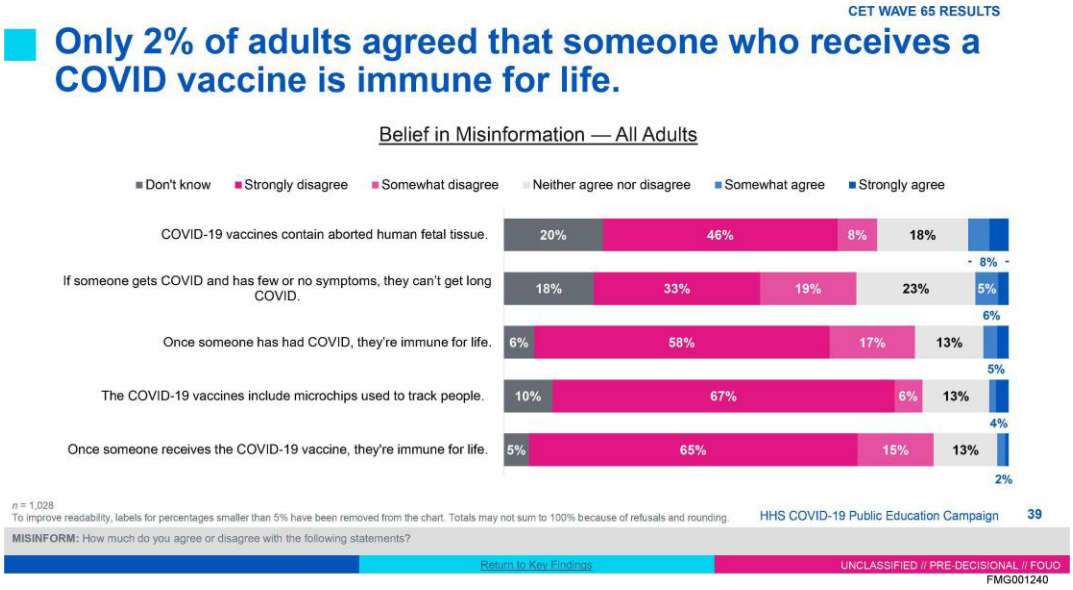
The Campaign also attempted to keep a close pulse on what they considered "misinformation." These included beliefs around vaccine development, safety, and efficacy, as well as COVID risk perception.



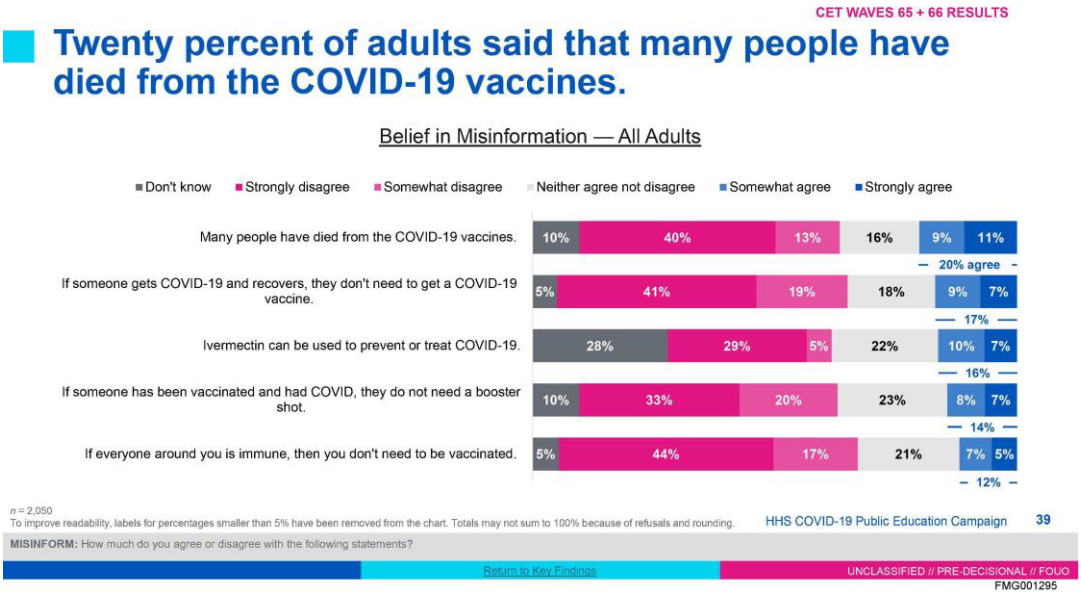
Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001237 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 66 Results (June 17-19, 2022), FMG001296 (on file with Committee).



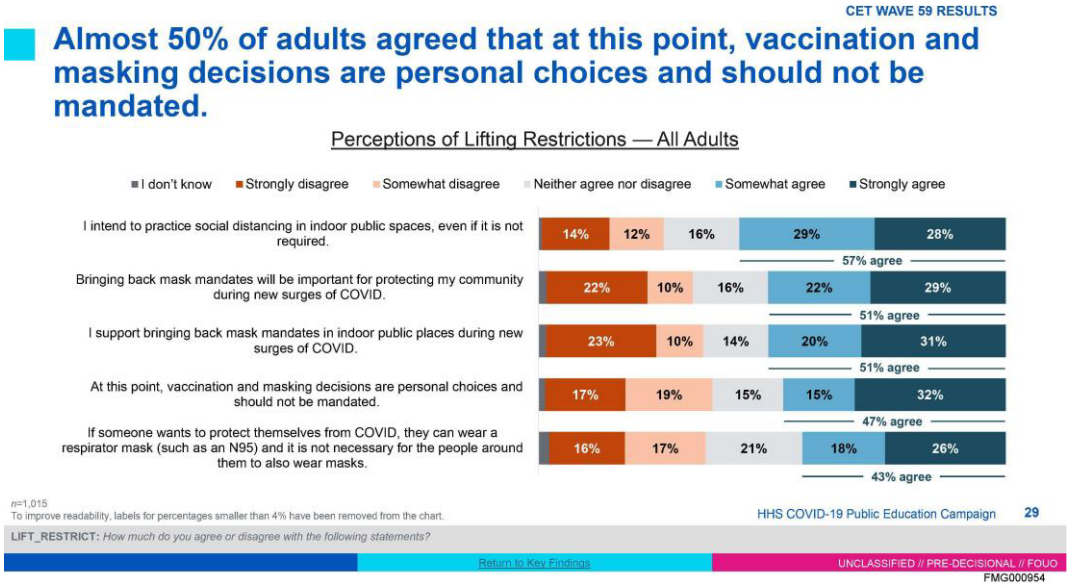
Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001240 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 66 Results (June 17-19, 2022), FMG001295 (on file with Committee).

Masks, Mandates, and Pandemic Fatigue

By 2022, many Americans had had enough. In April 2022, nearly half of all surveyed adults agreed that vaccination and masking decisions are personal choices and should not be mandated.[378] These statistics reveal how public perception significantly diverged from that of the Biden-Harris administration and the Campaign's messaging. Demonstratively, when the federal mandate requiring masks in airports and on airplanes, buses, subways, trains, and other forms of public transportation was scheduled to expire on April 18, 2022, the CDC, and the Transportation Security Administration (TSA) chose to **extend** it another two weeks—until May 3. Although major airlines such as Delta and American Airlines called to an end to the requirement, President Biden "promised to veto any legislation overturning it."[379]



Source: Fors Marsh Group, Current Events Tracker: Wave 59 Results (April 22-24, 2022), FMG000954 (on file with Committee).

One third of surveyed adults agreed that mask mandates should not be brought back, even with rising COVID cases, and nearly 40 percent agreed that the pandemic was winding down and that it was time to end all pandemic restrictions. Moreover, around 40 percent disagreed with bringing back proof-of-vaccine requirements for indoor public places during new COVID surges.

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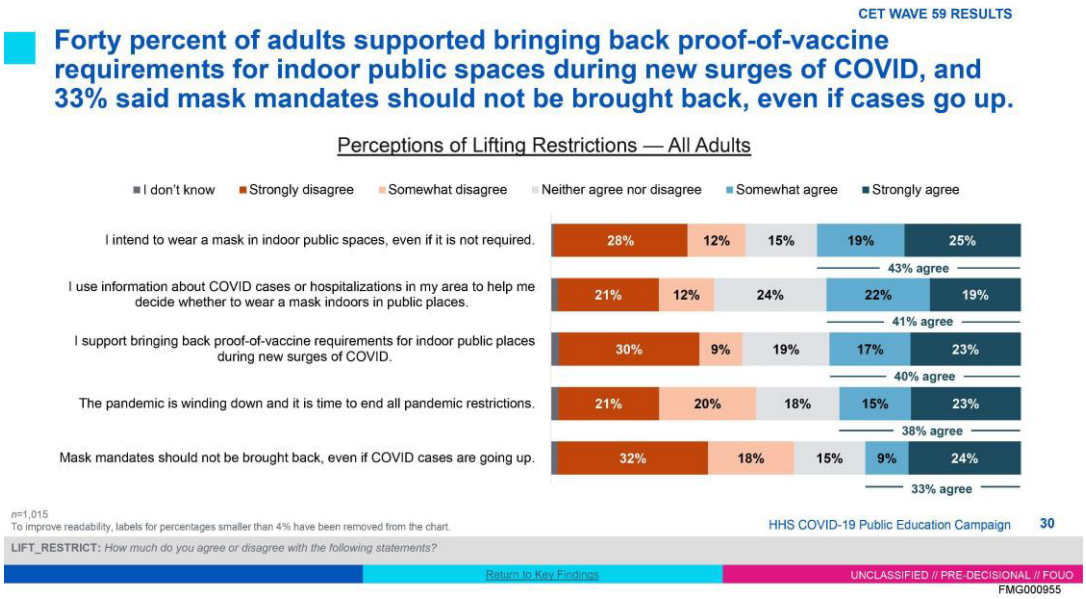
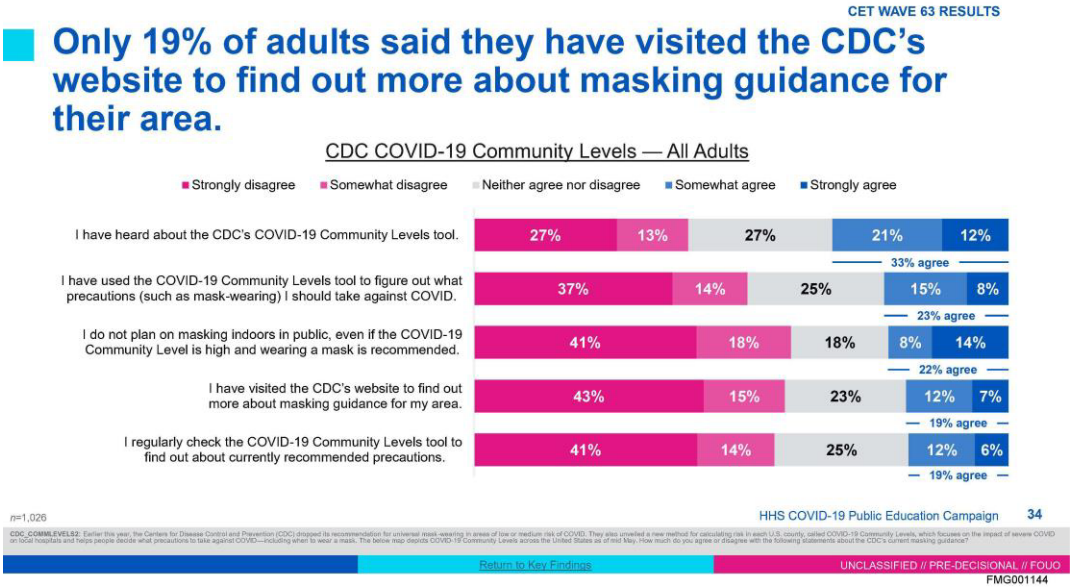
[378] *See* Fors Marsh Group, Current Events Tracker: Wave 59 Results (April 22-24, 2022), FMG000954 (on file with Committee).

[379] Katie Teague et al., *Where Are COVID-19 Mask Mandates Still in Effect?*, CNET (Apr. 13, 2022), https://www.cnet.com/health/medical/mask-mandate-where-are-masks-required/.



Source: Fors Marsh Group, Current Events Tracker: Wave 59 Results (April 22-24, 2022), FMG000955 (on file with Committee).

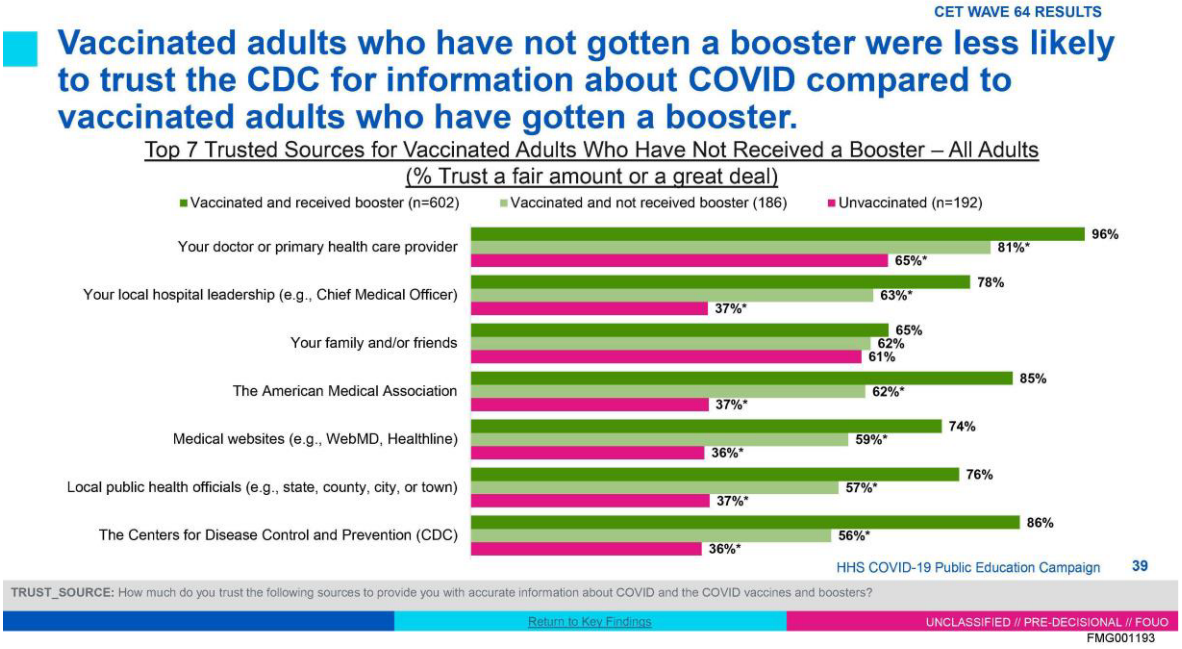
Additionally, surveys revealed fewer Americans were seeking out information on COVID from local TV news stations and even the White House.[380] FMG survey data showed few Americans were turning to the CDC website for guidance.



Source: Fors Marsh Group, Current Events Tracker: Wave 63 Results (May 20-22, 2022), FMG001144 (on file with Committee).

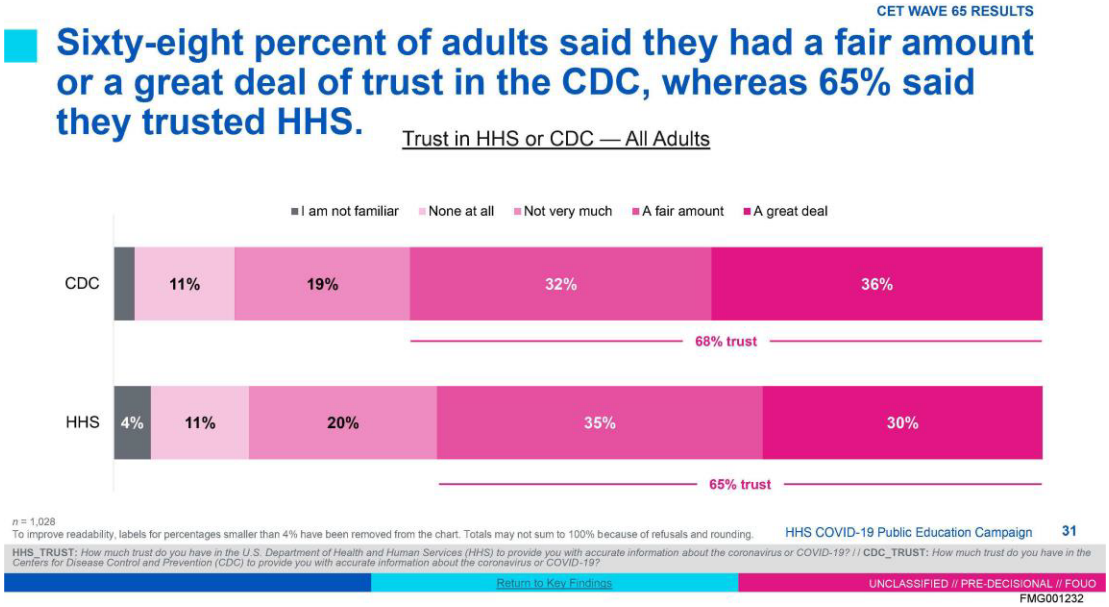
[380] Fors Marsh Group, Current Events Tracker: Wave 56 Results (April 1– April 3, 2022), FMG000812-13 (Apr. 8, 2022) (on file with Committee).

At the same time, vaccinated-but-not-boosted individuals were losing trust in the CDC.

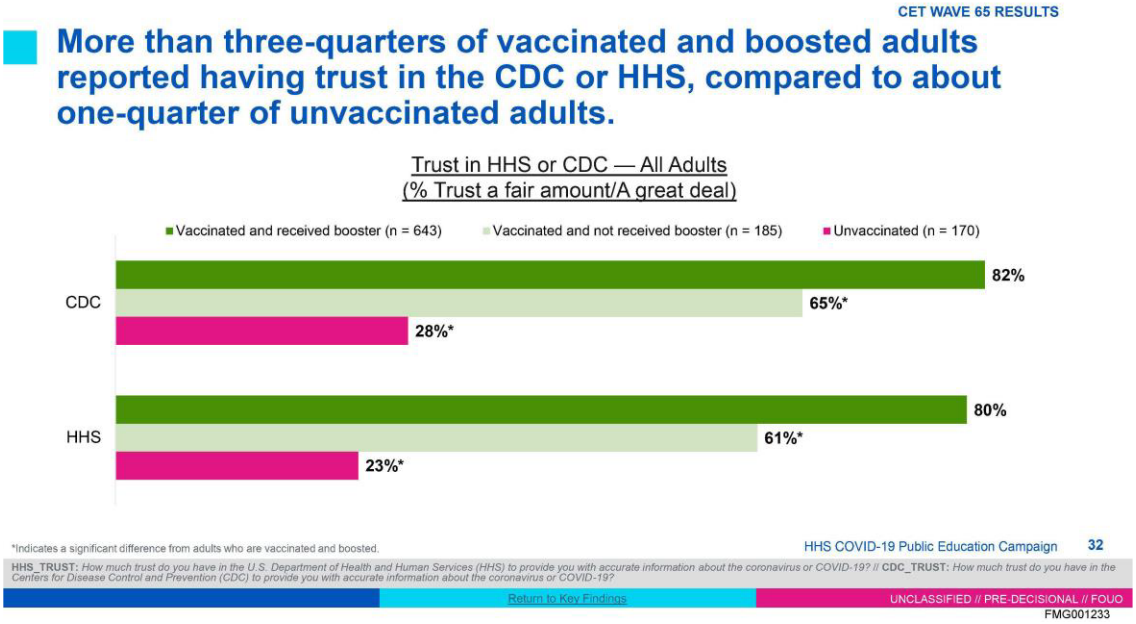


Source: Fors Marsh Group, Current Events Tracker: Wave 64 Results (June 3-5, 2022), FMG001193 (on file with Committee).

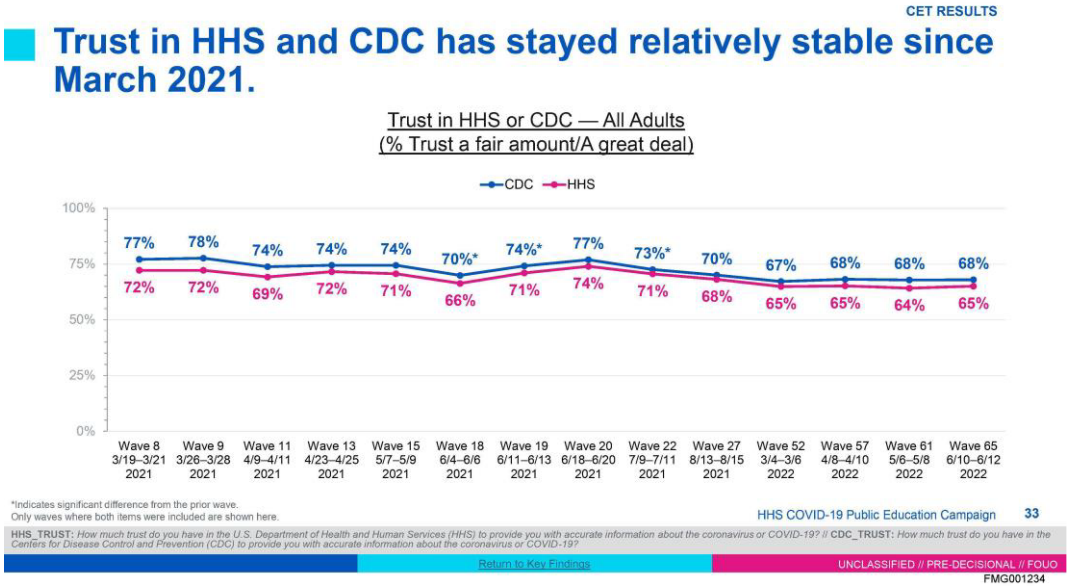
The Campaign repeatedly surveyed the public's trust in the CDC and HHS, providing the results of these assessments to agency officials as a means of validating Campaign messaging and agency enforcement actions. Notably, trust in the agencies was heavily dependent on an individual's own vaccination decisions: around a third of vaccinated-but-not-boosted adults and over three-quarters of unvaccinated adults did not have much trust in either the HHS or CDC. In contrast, over three-quarters of vaccinated and boosted adults expressed a great deal of trust in both the HHS and the CDC.



Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001232 (on file with Committee).



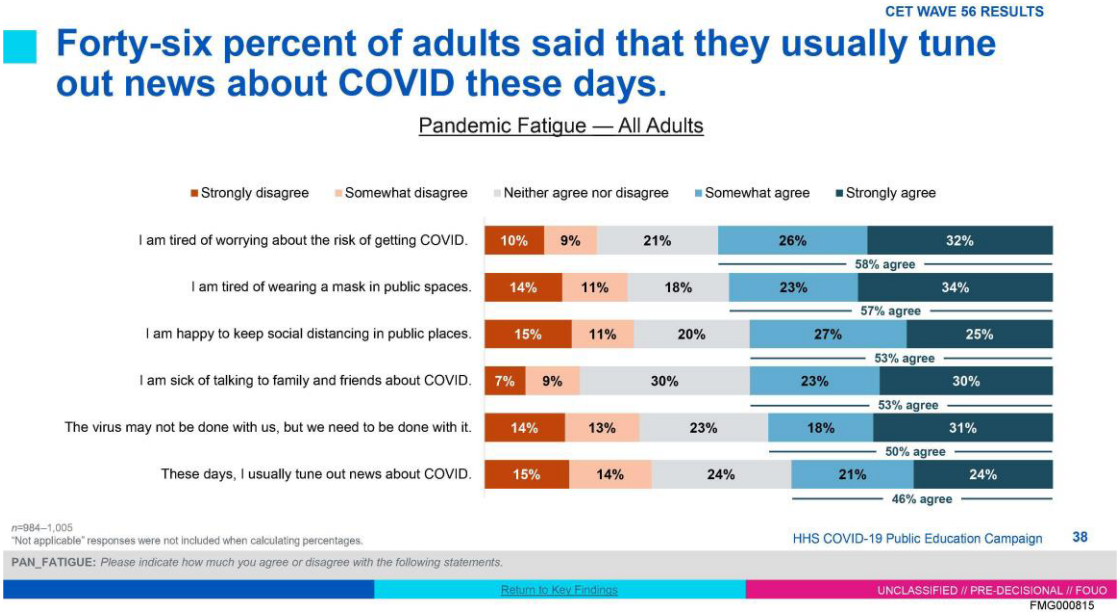
Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001233 (on file with Committee).



Source: Fors Marsh Group, Current Events Tracker: Wave 65 Results (June 10-12, 2022), FMG001234 (on file with Committee).

By April 2022, 58 percent of adults surveyed stated they were tired of worrying about the risk of COVID and 46 percent claimed they tune out COVID related news.[381] Fifty percent stated, "[t]he virus may not be done with us, but we need to be done with it."[382]

<u>Increasing COVID-19 Pandemic Fatigue, April 2022</u>



Source: Fors Marsh Group, Current Events Tracker: Wave 56 Results (April 1-3, 2022), FMG000815 (on file with Committee).

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[381] Fors Marsh Group, Current Events Tracker: Wave 56 Results (April 1– April 3, 2022), FMG000815 (on file with Committee).
[382] *Id.*